UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	Judge Patti B. Saris
ASTRAZENECA TRIAL	Chief Magistrate Judge Marianne B. Bowler

REPORT OF RAYMOND S. HARTMAN REGARDING ASTRAZENECA WITH RESPECT TO CLASS 1

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I. INTRODUCTION AND OVERVIEW

1. My name is Raymond S. Hartman. I am Director and President of Greylock McKinnon Associates (GMA), a consulting and litigation support firm located in Cambridge, Massachusetts. I am an economist specializing in microeconomics, econometrics and the study of industrial organization. I have taught economics, conducted economic research and provided economic consulting in my areas of specialization for thirty years. Since 1971, I have consulted to federal and state governmental bodies, private corporations, law firms, consulting companies, research organizations and international lending organizations. I have been a research referee for a variety of academic journals. I am the author of more than 100 refereed journal articles, book chapters and research/consulting reports. I have submitted oral and written testimony before federal and state courts of law and regulatory commissions. My testimony as an expert witness has addressed anticompetitive behavior, merger efficiencies, breach of contract, employment discrimination, patent infringement, class certification and the estimation of damages in a variety of markets and industries.

For additional details, Attachment A contains a summary of my qualifications, my curriculum vita and a current listing of testimony and/or appearances at deposition or trial. Attachment B is a listing of materials cited in this report.

2. I have been asked by Counsel to determine, using standard economic methodologies and the data which are sufficient for implementing such methodologies, the aggregate overpayment incurred by Class 1, as defined by Judge Saris,[1] for the drug Zoladex during the Class Period due to the alleged wrongful conduct of AstraZeneca ("AZ"). In doing so,

[1] *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Memorandum and Order re: Motion for Class Certification, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, August 16, 2005 (hereafter, *Memorandum and Order*), p. 87.

I have been asked to determine causation and liability. As a matter of economics, quantitative analysis and common pharmaceutical business practices, I conclude that liability can be so determined on a Class-wide basis for the purchases of Zoladex by Class 1, and that aggregate Class-wide damages can be calculated accurately and reliably using standard formulaic methodologies.

3. For Class 1, I have been asked by Counsel to assume that AWP is defined by the Court as a statutory matter. By this I mean that the term was intended to mean a published price that is an "average of wholesale prices." For the purpose of my testimony, I take this interpretation to mean that the "average of wholesale prices" was plainly intended to reflect the average acquisition cost of providers at wholesale, with some nuances developed in detail with the damage calculations below. I have also been asked by Counsel to assume for purposes of my analysis of Class 1 that price data furnished by AstraZeneca to determine reimbursements must take account of price reductions, cash discounts, rebates, free or reduced price services (where appropriate) and other discounts referred to in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers.[2] I note in passing that this OIG Compliance Program Guidance (hereafter *Compliance Program Guidance*) is generally consistent with the offsets required for calculating ASPs under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MPDIMA).[3]

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[2] Department of Health and Human Services, Office of Inspector General (OIG), Federal Register, Vol. 68, No. 86, 23731-23743 at 23733-34, (May 5, 2003).

[3] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, December 8, 2003.

The language presented by the OIG and in MPDIMA is generally consistent in their specification of how manufacturer's prices are to be reported.

According to the MPDIMA, Federal Register, Vol. 69, No. 4, Wednesday, January 7, 2004, Page 1091: "In the calculation of the manufacturers' average sales price, a manufacturer should include volume discounts, prompt pay

Taking these instructions as a point of departure, I have calculated the spread between the published AWP for each NDC and what should have been provided as the basis for pharmaceutical reimbursement (the average sale price, or ASP, to providers). I have done so using data produced by AstraZeneca. From these data, I have calculated spreads and what I will call statutory damages to Class 1.

4. I have also been asked as an economist to analyze the behavior of AstraZeneca to establish inflated AWPs for Medicare Part B reimbursable Zoladex while secretly lowering the acquisition cost to providers. I have concluded that such incentives did exist and that AZ engaged in tactics designed to aid sales of their drug by increasing the spread between the published AWP and the provider acquisition cost, thereby using spread as a profit center for providers.

5. I have also examined the issue of knowledge, *i.e.*, is there quantitative economic evidence that the members of Class 1 knew of AstraZeneca's *systematic* abuse of the AWP-based system for reimbursement of Medicare Part B drugs through large and arbitrary spreads between AWP and acquisition cost and through the tactics being used by AstraZeneca to utilize the spread as a promotional sales tool? I am aware of no evidence of such knowledge in deposition testimony of the relevant Class-members. I find no publicly-available evidence sufficient to inform Class-members of AZ's practices in this case. I have also examined the issue of

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discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid program)."

According to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, page 12 and Department of Health and Human Services, Office of Inspector General, Federal Register, Vol. 68, No. 86, 23731-23743 at 23733-34: "Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues)."

government knowledge. The available economic data, consisting of published survey research and negotiated contracts, indicate to me that spreads were generally believed by CMS and other agencies to be in a range that supported negotiated reimbursement rates of AWP ± 15% in contracts and AWP – x% for single-source physician-administered drugs in the survey research, where generally x% was at most 20%. I find that actual spreads were often far in excess of the spreads that could be deduced from available market information and that the measures I use to characterize overall market expectations are conservative. I do not find evidence that the government knew of or approved of AstraZeneca's marketing practices. To the contrary, the government attempted to ascertain true acquisition costs over a long period of time. There is no evidence AZ disclosed these practices to the government or to consumers.

II. THE MEDICARE PART B PROGRAM AND ITS RELIANCE ON AWP FOR COST-BASED REIMBURSEMENT

6. Class 1 reimbursement is dependent upon the Medicare payment system for Part B drugs. I have researched the history of that payment system and discuss it below as background for clarifying the financial incentives at the heart of the AWP Scheme. Such research into the regulatory and statutory background of an industry is common for economists analyzing that industry and its competitive landscape. It is certainly a prerequisite for any economist rendering opinions about the markets at issue here, since conduct and pricing in these markets diverge importantly from the competitive paradigm. Consequently, incorrect application of simple competitive theories can produce inappropriate and incorrect conclusions.

7. The Medicare program was established in 1965 as an amendment to the Social Security Program. Medicare provides health insurance to persons age 65 and older, to qualifying

persons under 65 with certain disabilities and to persons of any age suffering from permanent kidney failure. Medicare is the nation's largest health insurance program, covering over 39 million people in 2003. Through 2005 it was composed of three parts: a Hospital Insurance Program (Part A), the Supplementary Medical Insurance Program (Part B), and a managed care program (Part C, once called "Medicare Plus Choice" and now called "Medicare Advantage") that offers enrollees the opportunity to join a commercial health plan instead of receiving coverage through Parts A and B.[4] Part B, which primarily covers physician services, is optional. Most Medicare beneficiaries choose to enroll in Part B and either pay the premium themselves or have it covered by a former employer or Medicaid. Medicare coverage, including Part B, is generally subject to a deductible and a 20 percent coinsurance requirement. Many Medicare beneficiaries also purchase private supplemental coverage to pay for Part B coinsurance. Some employers offer supplemental coverage to their retirees and certain low-income Medicare beneficiaries qualify to receive Medicaid coverage for their coinsurance.

8. When implemented, Medicare was modeled on the major medical plans then popular in the private sector. The private plans were primarily intended to cover catastrophic health care costs with substantial cost sharing at the front end (*i.e.*, deductibles and coinsurance). Like most employer-sponsored plans in 1965, Medicare did not offer routine coverage for outpatient prescription drugs. However, a small group of specialty drugs was and continues to be covered under Medicare Part B. These drugs typically are administered by physicians in the

[4] For Part C insureds, the private health plan takes the risk for all reimbursement, including physician-administered drugs. Those insureds would therefore not be included in Class 1. Part D is the self-administered prescription drug benefit that took effect on January 1, 2006. The implementation of Part D has occurred beyond the Class Period, and I do not analyze it.

office setting or in hospital outpatient departments, although some self-administered drugs are also covered.

9. Reimbursement for prescription drugs under Part B in the Medicare program has been based on the Average Wholesale Price (AWP)[5] reported by drug manufacturers and published in the standard directories (Red Book, First Databank (Blue Book) and Medispan). While the precise formula for AWP-based reimbursement has changed over time, reliance on AWP was a constant until January 1, 2005, when the reimbursement basis was changed to 106%*ASP (average sales price) by the Medicare Prescription Drug Improvement and Modernization Act of 2003.

10. More specifically, the Social Security Act Amendments of 1965 (P.L. 89-97) explicitly link reimbursement to cost as follows:

> "The amount paid to any provider of services with respect to services for which payment may be made … shall … be the reasonable cost of such services…"[6]

11. I understand that the original intent of Congress was to pay a reasonable amount to providers for the care of Medicare patients.[7] In a 1995 article, Robert Ball, who served as commissioner of Social Security under Presidents Kennedy, Johnson, and Nixon, provides an

[5] "Apparently from the beginning of the program, Medicare has based payment for drugs on published 'average wholesale price' (AWP). AWP is used throughout public and private insurance programs as the basis for drug reimbursement, both for drugs administered in physician offices and for drugs dispensed by pharmacies. The amount of reimbursement varies from plan to plan and setting to setting, but it is almost always expressed as a percentage of AWP." American Society of Clinical Oncology (ASCO), "Reform of the Medicare Payment Methods for Cancer Chemotherapy," May 2001, p. 5.

[6] In connection with hospital inpatient expenses, see § 1814 (b) of the Social Security Act Amendments of 1965 ("Medicare"). In connection to supplementary benefits of the Act, it is stated in Part B § 1833 (a) that "… there shall be paid ... [for] each individual who is covered … amounts equal to … 80 percent of the reasonable charges …"

[7] Donald F. Beck, *Principles of Reimbursement in Health Care*, Aspen Publication, Rockville, MD, 1984, p. 3.

insider's insights concerning the intentions of Medicare legislators.[8] In connection with all hospital care, he states that:

> "By and large, our posture at the beginning was one of paying full costs and not intervening very much in how hospitals, at least the better ones, conduct their business … We believed in paying fully. We opposed shifting costs to other payers, and we avoided discounts beyond what our contractors might have secured for their own insured persons."

In connection with out-patient physician services, he states that:

> "Reimbursement was to be a 'reasonable' charge determined by the customary charges of the particular physician and the prevailing charges in the locality for similar services."

12. Reliance upon cost-based measures for reimbursement (for physician services under Part B) was further formalized in the early 1990s by the Centers for Medicare and Medicaid Services (CMS) through research undertaken to develop resource-based relative-value scales (RBRVS). RBRVS were developed in cooperation with representatives of the American Medical Association to provide methods of determining amounts to reimburse physicians under Part B for the thousands of provider procedures performed as summarized by CPT codes. CMS maintains and modifies over time the RBRVS, thereby allowing for the alteration of reimbursement amounts in light of changes in relative and overall medical costs and the relative value of the particular procedure. As a result of Medicare's reliance upon a RBRVS, reimbursement amounts *are designed to be and expected to be related in a predictable way to costs*, a predictable way that can be translated into yardsticks. I explain the economic basis of the

[8] Robert M. Ball, "What Medicare's Architects Had in Mind," *Health Affairs*, 14(4), 1995, pp. 62-72. The specific quotes that follow in this paragraph are found on pp. 68-69.

CMS RBRVS in more detail in Attachment C to this Report, and its relationship to yardsticks for the reimbursement of physician services and drugs under Part B.[9]

13. The cost-based reimbursement procedures used by Medicare carriers prior to January 1, 1998 to determine the amount allowed as reimbursement for a covered drug were based on the lower of the Estimated Acquisition Cost (EAC) or 100% of the national AWP for that drug. The EAC, and its concordance with AWP, was to be determined based on surveys of actual invoice prices paid for the drug and thus designed to represent the actual cost (or "usual and customary charges") of drugs for direct purchasers (the providers, in the case of Medicare Part B drugs).

14. Historically, however, Medicare carriers did not conduct such surveys and, instead, based reimbursement on reported AWPs,[10] despite the fact that Congress intermittently has revisited the need for such studies.[11]

This reliance upon reported AWPs in the absence of surveys is understandable given the "information" available through AWP-price-reporting services in the market and the administrative efficiency of using that information. The underlying belief that those reported AWPs were "provider-cost-based measures" for Medicare was buttressed by the assertions of the publishers themselves. For example, the promotional materials for First DataBank (FDB), the

[9] In Attachment C, I demonstrate that the CMS RBRVS system is designed to provide the economic foundation for provision of medically appropriate provider services. I demonstrate that it would be economically irrational for Medicare (indeed, any payor) to rely upon a reimbursement system that did not yield reasonable relative values such as those provided by the RBRVS.

[10] See "Excessive Medicare Payments for Prescription Drugs," Office of Inspector General, Department of Health and Human Services, December 1997, OEI-03-97-00290, p. 1.

[11] The Benefits Improvement and Protection Act (BIPA) of 2000 recognized in passing that more studies were needed to determine "the average prices at which … drugs … are acquired by physicians and other suppliers."

single most important provider of electronically integratable drug price information during much of the Class Period[12] asserted the following:

> "I have had many conversations regarding what 'AWP' is and how First Data determines it. There is much folklore and misunderstanding as to the determination of AWP and how we obtain the data.
>
> AWP is the average wholesale price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC). The operative word is *average*. AWP was developed to provide a price, which all parties could agree upon.
>
> In order to determine the AWP, First DataBank surveys national wholesalers to ascertain what they use as a price basis in their AWP price files. We contact the wholesalers to determine what the markup should be for a new company or to confirm that the markup we are applying is current. A survey may be performed on a single NDC number or on a manufacturer's entire product line. In either case, each national wholesaler is surveyed on a number of products from each manufacturer.
>
> The number of surveys is increasing. First DataBank surveys drug wholesalers that represent over two-thirds of the wholesaler total dollar volume. The markup that First DataBank utilizes is representative of wholesalers on a national level. Because individual wholesalers may mark up each manufacturer differently, a weighted average, not a consensus average, is calculated. That is, the market share held by the wholesalers surveyed affects the markup factor proportionally. Wholesalers with higher drug dollar volumes have more weight in the determination of the final markup. Thus, a higher degree of certainty is achieved" (emphasis in original).[13]

[12] The FTC found that FDB had a monopoly on the market for integrateable electronic price data bases reporting AWP and WAC during the period 1998 through FTC's forced divestiture of MediSpan by FDB in late 2001; see Complaint for Permanent Injunction and Other Equitable Relief Pursuant to Section 7A(g)(2) of the Clayton Act and Section 13(b) of the Federal Trade Commission Act, *Federal Trade Commission v. The Hearst Trust, The Hearst Corporation and First Databank, Inc.*, United States District Court for the District of Columbia, Civ. No. 1:01CV00734. However, I understand that a data sharing agreement between FDB and MediSpan continued FDB's monopoly provision of integrateable electronic AWP price data until October 2004.

[13] Cited at ¶ 78 of Berndt, Ernst R., Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, February 9, 2005. See also *New England Carpenters Health Benefits Fund; Pirelli Armstrong Retiree Medical Benefits Trust; Teamsters Health & Welfare Fund of Philadelphia and Vicinity; and Philadelphia Federation of Teachers Health and Welfare Fund v. First Databank, Inc., and McKesson Corporation*, United States District Court District of Massachusetts, C.A. No. 1:05-CV-11148-PBS, "Average Wholesale Price," FDB-AWP 02023 and "PriceAlert, The Official Guide to AWP Pricing," 3/15/2000, FDB-AWP 15102-4. When marketing its products, FDB made it known that its AWP was the market standard, stating it "provides you the same AWP prices used by Aetna, PAID PCS, MEDI, MET, most Blue Cross Blue Shield Plans, wholesalers and approximately 49 Medicaid programs" (FTC Complaint, *op. cit.*, ¶ 103). As we know now, this characterization of AWP is wrong. However, it is clear that much of the industry relied upon such promotional claims in the past.

15. On January 1, 1998, 42 C.F.R. § 405.517 was amended so that the allowed amount would be based on the lower of the billed charge on the Medicare claim form or 95% of AWP. In practice, the notion of the "billed charge" was the acquisition cost of the drug to the provider.[14] In practice, reimbursement has been paid using 95% of the AWP.

16. On January 1, 2003, the CMS implemented a "Single Drug Pricer" (SDP) policy that created a uniform system of prices for drugs covered by Medicare Part B based on 95% of AWP, continuing the Medicare drug-pricing system's reliance on AWP.[15] At the same time, CMS authorized its carriers (the Medicare Payment Safeguard Administrators, MPSAs) to pay for certain drugs based on the price (AWP) of the "least costly alternative" (LCA), a procedure which has had particular relevance to the drug at issue here.[16] While the LCA has been used

[14] I base this assertion on the following fact discovery and testimony.

- CMS statements. For example, in his March 21, 2002 testimony to the U.S. House Energy and Commerce Subcommittees on Oversight & Investigations and Health on Part B drug reimbursement, Thomas Scully, CMS Administrator, states "These drugs are typically provided in the hospital outpatient setting, dialysis centers, or in the doctor's office, and are purchased directly by the physician or provider. … By law, we generally pay for these drugs based on the actual charge or 95 percent of the AWP, whichever is lower." He confirms this position in similar testimony to the Senate Finance Committee Subcommittee on Health, March 14, 2002.
- The alternative reimbursement basis before 1998 was EAC. The alternative basis returned to EAC (ASP) in 2005.
- This understanding is reflected in Defendants' expert Steven Young's testimony: "From 1992 to date, moreover, reimbursement under Medicare Part B has generally been made at the lower of the billed charge amount or AWP (through 1997) or 95% of AWP (after 1997). The Carriers may reimburse at less than the AWP based rates where, for instance, the physicians' billed charges are less" (Steven Young Rebuttal Declaration, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, October 25, 2004, at ¶ 170).

[15] Centers for Medicare & Medicaid Services, "Single Drug Pricer (SDP)," Program Memorandum: AB-02-174, December 3, 2002.

[16] Medicare Carriers Manual, § 2100.2(B). The Least Costly Alternative (LCA) provision requires that a local Medicare carrier not cover the additional cost of a more expensive product if a clinically comparable product costs less. Therefore in states where a carrier applies the LCA policy, physicians that administer the more expensive drug will be reimbursed at an amount related to the AWP of the less expensive drug. Carriers' use of LCA is supported by CMS in its Program Integrity Manual (Chapter 13, Section 5.4), as quoted in "Medicare Reimbursement for Lupron," Office of Inspector General, Department of Health and Human Services, January 2004, OEI-03-03-00250:

> "Least costly alternative is a national policy provision that must be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principal to payment for non-DME services as well" (p. 2).

selectively since 1997, its use has certainly not become universal for all Medicare carriers and all groups of therapeutic substitutes.[17]

17. The Congress further revised Part B drug reimbursement in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (hereafter, *MPDIMA*). Over the period since Medicare's inception and most importantly during the 1990s, the relevant Medicare agencies (HCFA, CMS) were presented with increasingly compelling and consistent information sufficient to make clear that while AWP historically may have reflected provider acquisition cost, and while the AWP continued to be described by the major integratable electronic price data source (FDB) as the "weighted average wholesale price" (see ¶ 14 above), AWP was no longer the reliable benchmark it had been and had been believed to be. Rather, the AWP system had proven to be subject to such extensive abuse that an alternative method of cost reimbursement was believed appropriate. The *MPDIMA* recognized this fact and the desirability of returning reimbursement to a measure of costs less susceptible to manipulation – the calculated, average sales price to the providers. Specifically, the basis for drug reimbursement was changed to 106% of the "Average Sales Price" (ASP), rather than the former 95%-of-AWP standard. For the year

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LCA, first implemented for Lupron in South Carolina in 1997, has determined Part B reimbursement for Lupron and Zoladex – both LHRH agonists used in the treatment of advanced prostate cancer. The drugs are clinically comparable; therefore, the carriers will only reimburse up to the allowable reimbursement rate (AWP-based) for Zoladex, the cheaper of the two drugs. Any physician who administers Lupron to a Medicare patient only receives the allowable AWP-based reimbursement rate for Zoladex. As of January 2004, Medicare carriers in 47 of 57 jurisdictions apply a least costly alternative policy for Lupron; see "Medicare Reimbursement for Lupron," *op. cit.*, p. 5.

[17] A recent attempt by Medicare insurance carriers in Florida, Illinois, Indiana, Kentucky, Louisiana, Ohio, Pennsylvania, South Carolina, and Texas to implement an LCA policy for Zemplar, an intravenous drug prescribed for dialysis patients, was being challenged as of 2002 and had failed in Florida. See Maureen Michael, "Is the Medicare Policy in Several States to Restrict Access to Vitamin D For Dialysis Patients Heading in the Wrong Direction?," Focus on Nutrition: Opinion, Contemporary Dialysis & Nephrology, http://www.ikidney.com/iKidney/InfoCenter/Library/CDN/Archive/VitaminD0802.htm, accessed August 6, 2004.

2004, while transitioning from AWP to ASP, the basis for drug reimbursement was set at 85% of AWP, with some variation for particular drugs and biologicals.[18]

III. THE ECONOMIC INCENTIVES OF A DRUG COMPANY TO UNDERTAKE THE AWP SCHEME

A. Overview – Spread Competition through AWP Inflation

18. The alleged fraud was possible in this case because of three simple facts and one observation developed in Section II above. Fact 1 is that Medicare reimbursement generally and for Part B drugs specifically was originally and formally designed to be cost-based and was believed by payors to be cost-based for a long period of time. Fact 2 is that CMS believed that AWPs were administratively efficient and sufficiently reliable indicators of relative costs to meet the requirements of a relative value scale reimbursement system (see ¶ 12 above and Attachment C). Fact 3 is that CMS rationally exhibited inertia with respect to the incrementally accumulating information on diverging spreads between AWP and provider acquisition costs (as I develop in Section V below). Until the statutory changes enacted in 2003, CMS found the accumulating information incomplete and not sufficiently systematic to warrant entirely revamping its AWP-based reimbursement practices and procedures. The one observation is that if these facts did not generally characterize Medicare and payor expectations and understandings under Part B reimbursement, it would have been economically irrational for Medicare and TPPs to continue to reimburse under that AWP-based system.[19] The accumulating evidence on the

[18] See footnote 34 below.

[19] For example, if reimbursement were not cost-based in a relative value scale, incentives for inappropriate drug dispensing would be created, contrary to Medicare's self interest. For research showing the effects of relative differences in drug profitability upon therapeutic choices, see Mireille Jacobson, A. James O'Malley, Craig C. Earle, Juliana Pakes, Peter Gaccione, and Joseph P. Newhouse, "Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?" *Health Affairs*, Mar/Apr 2006, Vol 25, No. 2, pp. 437-443. For a discussion of the effects of

payment distortions associated with continuing to use the AWP as a relative value scale were finally formally recognized with the 2003 *MPDIMA*.

19. It is alleged that AstraZeneca understood these three facts and the resulting observation better than CMS, Medicare and Class member payors. It knowingly exploited them by artificially inflating the list price of Zoladex (its AWPs and by implication any list prices formulaically linked to AWP) above the actual acquisition cost (AAC = ASP) of the providers, thereby increasing the "spread" (or "Return to Practice," as the spread was called in the Lupron litigation[20]) earned by the provider of the drug and measured as the difference between provider reimbursement and drug acquisition cost. This increased spread affirmatively incentivized the relevant providers to prescribe the drug in question relative to alternative therapies, everything else equal, a belief confirmed by AstraZeneca's strategic materials discussing spread for Zoladex (see Section III.D below).

20. These allegations suppose that those entities being incentivized could and would move market share. Considerable discovery materials, industry literature and academic research support these allegations.[21] This Court has explicitly recognized this alleged behavior, stating[22]

> "Because doctors are involved as both retailers and as prescribing physicians, manufacturers, realizing the purchasing power of physicians, provide them with

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relative prices of services more generally, see Paul B. Ginsburg and Joy M. Grossman, "When the Price Isn't Right: How Inadvertent Payment Incentives Drive Medical Care," *Health Affairs*, Jul-Dec 2005, Vol. 24, pp. 376-384..

[20] Fraudulent manipulation of the "spread" in precisely this fashion was the primary allegation in the U.S. Government's litigation against the manufacturer (TAP Pharmaceutical Products, Inc., or TAP) of the physician-administered drug Lupron. TAP pled guilty to fraudulent manipulation of the spread between AWP and the actual acquisition cost (AAC) of Lupron and paid in settlement damages of $875,000,000 plus interest; see Sentencing Memorandum of the United States, *United States of America v. TAP Pharmaceutical Products, Inc.*, United State District Court for the District of Massachusetts, Eastern Division, Criminal Action, No. 01-CR-10354-WGY (hereafter *Lupron Sentencing Memorandum*). The "spread" is referred to as the "Return to Practice" by TAP, and the Government made use of this term throughout the *Lupron Sentencing Memorandum*.

[21] See footnote 19 for two recent academic articles further supporting this finding.

[22] *Memorandum and Order*, pp. 30-31.

> rebates, leading to large profits for the doctors on the prescription and administration of certain drugs. These profits now allegedly comprise a large percentage of these doctors' income; according to Hartman, two thirds of the income of practice-based oncologists comes from the mark-up on injectable drugs. … Some experts have commented that 'the financial incentives created by this profitability played a large and problematic role in prescribing decisions' from 1998-2003 because 'prescribers responded to these high margins by tending towards administering more (and more expensive) drugs than might be medically necessary or optimal for the health of the patient.' …
>
> In summary, when medical benefit expenditure data are poorly monitored and 'tracking patient data is nearly impossible', and when this is widely known, possibilities for mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit (Berndt ¶ 191)."

21. I discuss below (Section III.D) the extent to which AZ believed and relied upon the AWP scheme to incentivize physicians to move market share and thereby benefit from the alleged scheme. I note that the spread could be manipulated by either artificially inflating the AWP (to which reimbursement was formally linked under Part B) everything else equal; by reducing ASP, everything else equal; or by doing both. Both methods of increasing the spread were recognized in the 2003 Report to the Congress from the Medicare Payment Advisory Commission (MedPAC) as follows:[23]

> "In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. For these drugs, **manufacturers compete to increase their market share. This competition can take two forms. A manufacturer may raise the AWP for its product without changing the price charged to purchasers.** Although the manufacturer's profit per dose will not increase with the rise in the listed price, the bigger difference between providers' acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer's product over its competitor. At the same time, coinsurance payments charged to beneficiaries will rise as the AWP increases. A

[23] Medicare Payment Advisory Commission (MedPAC), Report to the Congress, *Variation and Innovation in Medicare*, June 2003 (*MedPAC Report*), pp. 156-157.

> hearing before the House Energy and Commerce Subcommittee on Health highlighted this outcome on September 21, 2001. One chemotherapy drug, Vincasar, which had an AWP of $740, was sold to physicians for $7.50 per dose. The beneficiary's copayment (about $150) was about 20 times providers' acquisition cost. **Possibly in response to increasing scrutiny of drug pricing practices by the courts, some manufacturers have adopted an alternative marketing strategy. They leave the AWPs at existing levels, and offer larger discounts directly to physicians who choose their drugs** over products offered by competitors. In this case, the manufacturers' profit per unit dose will be less, but overall profits increase if the discounts result in increased market share. On May 5, 2003, the Office of Inspector General (2003) issued voluntary compliance guidelines for pharmaceutical manufacturers.[24] If a manufacturer manipulates the AWP to increase federal payments to its customers, the federal antikickback statute is implicated. In other words, it is illegal for a manufacturer knowingly to establish or maintain an AWP if one purpose is to manipulate the spread to induce customers to purchase its products" (emphasis added).

Of course, from AZ's perspective, the most profitable strategy to increase spread would be to artificially inflate the AWP, holding ASP constant. In that case, AZ would not decrease the revenue per unit sold while still increasing the incentives to move market share. However, AZ could also lower its ASP to manipulate the spread. As I discuss below, AZ made use of both tactics.

22. To date, the most publicized example of fraudulent AWP price inflation has been litigation against TAP Pharmaceuticals for their drug Lupron. The methods by which the "spread" or "Return to Practice" (RTP) was fraudulently manipulated and increased by the manufacturer of Lupron (TAP) and how that spread incentivized providers such as urologists and oncologists to prescribe Lupron over alternative therapies have been well documented and admitted by Defendants in that matter and are helpful in understanding what occurred here as well. AWP was increased well above the estimated acquisition cost (EAC) or the average sales price (ASP) to the providers. Provider reimbursement rates were linked to AWP; ASP was

[24] That is, the *OIG Compliance Program Guidance*.

decreased by substantial discounts, rebates, off-invoice payments and some admittedly illegal practices; TAP instructed the physicians dispensing Lupron and earning the inflated Return to Practice not to mention the aggressive price discounting to other doctors, to HCFA or to other payors (as discussed more fully in Section III.B below).[25] The resulting spread did incentivize the appropriate economic entities (physicians) to increase sales of Lupron relative to alternative therapies; market sales and market share were increased thereby. Indeed, some oncologists who earned millions of dollars in incentive payments from the "spread" or "Return to Practice" were named Defendants.

23. Since AZ's drug, Zoladex, is Lupron's principal therapeutic competitor, it is not surprising that AZ adopted the same "Return to Practice" strategy to compete with Lupron.[26] The independent expert to the Court, Dr. Berndt, has characterized this behavior (at his p. 46) as specific "egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians." AZ also entered into a settlement agreement with the federal government for such fraudulent marketing practices.[27]

B. Spread Competition in This Matter Differs from Standard Price Competition and Does Not Benefit Consumers or Payors

24. Aggressive spread competition was implemented by AZ in 1995, when it realized that its major competitor Lupron had been inflating the spreads on Lupron to capture market share. However, it must be noted that this type of competitive response is not to be confused with normal price competition. While the spread competition in this matter may have involved

[25] All of these allegations are discussed in the *Lupron Sentencing Memorandum*.

[26] The *MedPAC Report*, o*p. cit.* formally discusses the spread competition between TAP and AZ with respect to Lupron and Zoladex at p. 158.

[27] Memorandum of Plea Agreement, *United States of America v. AstraZeneca Pharmaceuticals LP*, In the United States District Court for the District of Delaware, Criminal Action No. 03-55-JJF, June 20, 2003 (Plaintiffs' Exhibit 1).

competitive price reductions, it did not result in pro-competitive price reductions to consumers, as is usually the case when price competition occurs. As a matter of economics, in a competitive market, consumer welfare is increased when costs are reduced; prices reflect those cost reductions and consumers switch to those products with lower prices/costs. In this industry, manufacturers' ASPs and actual acquisition costs to providers and market intermediaries **were reduced**, but consumers/payors were either steered or switched to those products that were priced higher (i.e., required higher reimbursement rates), or they paid a higher price related to an inflated AWP, or they continued to pay for drugs at the same prices that did not reflect cost reductions. Such a market result is diametrically opposite to a normally competitive market result. Yes, spread competition occurred in response to competitive behavior; however, as with Lupron, it was the manner by which the competition was implemented that constituted fraudulent marketing practices. The spread competition exploited by AstraZeneca in this case is not normal pro-consumer competition. Any attempt to characterize it as such would be misleading.

25. While standard price competition does not require that consumers know, or have expectations about, the costs of the competing suppliers in a market, successful price competition does require signaling consumers about the lower prices offered by the competitors seeking to gain market share. The spread competition alleged in this matter was successful precisely because competing suppliers actively and secretly suppressed information **from end payors** about the lower prices offered providers. Those lower prices were offered to middlepersons (through discounts, price offsets and/or free samples to be sold illegally) not to consumers or end payors. Selected relevant examples include the following:

a) The *Lupron Sentencing Memorandum* (at pages 25-26) describes "the training program … by top Sales management at TAP … regarding pricing strategy" as follows:

- "One of the slides, regarding pricing strategy, contains the following:

  'What should I say to my physicians about contract confidentiality?

  Explain to physicians that discussing price could potentially put reimbursement in jeopardy.

  Doctor by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCF [*sic*] then realized that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amount you may charge.'

- On the PowerPoint slide for the instructor, the following text appears:

  'The main point to make to physicians is that confidentiality clause is a protection for them. If word is leaked back to HCF[*sic*]/ Medicare that the cost of Lupron is going down, they very well may take steps in reducing allowable. This tactic should help prevent physicians talking amongst themselves.'

- TAP's entire program of discounts – designed initially to replace the free product discount program – was premised upon the notion that doctors would not pass along any discounts they received in purchasing to patients and their insurers, including Medicare. The Government has concluded that, just as TAP and its employees did not expect physicians to pass along to their customers any price discounts, TAP and its employees also did not expect doctors to pass along any free drug 'discounts' and fully expected and intended doctors to bill patients for free drugs."

b) AZ likewise inserted provisions in its buying group contracts with physicians that the providers would have to maintain the confidentiality of the terms and conditions of

the contracts for a period of three years.[28] David R. Brennan, AZ's President, testified that this was AZ's policy.[29]

"Q. Was there a procedure in place for AstraZeneca to publish the prices that were arrived at in urology group buy contracts to the marketplace?
A. I'm not aware that that is something we would do, no.
Q. In fact, it is something you didn't do, right?
A. Yes.
Q. They were actually confidentiality clauses in the urology group contracts, right?
A. Sounds like it, yes."

He likewise testified that AZ made no effort to communicate the discounts it gave to providers to individuals who were administered Zoladex.

"Q. But the payors did not know what you were selling Zoladex to doctors for, right? …
A. I mean, if there is confidentiality associated with it, then we certainly wouldn't be the ones to do it. But I think everybody was aware that there were discounts from AWP and from WAC.
Q. Everyone was aware. The consumer getting a shot of Zoladex was aware of the discount? …
Q. Yes or no?
A. I don't know the answer to that.
Q. Do you think so? Do you think so? Do you think the consumer getting a shot of Zoladex in his abdomen knew that the percentage of the co-pay he had to pay was higher than it would have been had the reimbursement been based on the actual acquisition cost of the drug rather than AWP? Do you think the consumer knew that?
A. I don't know. I honestly can't say I know. I mean, I think that there was incentive in the system. There was co-pays in the system. It is difficult to say, for me to say that I know exactly what somebody who was getting a shot would know.
Q. Was there ever an effort made by AstraZeneca to let the consumer know exactly what it was that their doctor purchased the drug for?
A. Not that I am aware of."[30]

[28] See, *e.g.*, May 1, 1996 Contract with Urology Network of Central Ohio, Plaintiffs' Exhibit 244 (AZ0069688-701).

[29] Deposition of David R. Brennan, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, February 14, 2006, pp. 29-30.

[30] *Ibid.*, pp. 30-31.

26. The markets and competition in the markets at issue in this litigation are not analogous to the markets and competition in the markets for such consumer products as eggs, soda pop or automobiles, as AstraZeneca would like the Court to believe.[31] The markets for the first two consumer products are sufficiently competitive that prices will be driven in equilibrium toward costs, whether or not consumers have expectations about or knowledge of those costs. Price information is aggressively and accurately disseminated through mailings, flyers and a variety of media sources explicitly informing consumers of price reductions aimed at capturing market share. That is the nature of price competition. The information available to a consumer purchasing a new automobile is also extensive. Resale market prices of similar makes and recent vintages are available through such information sources as the Blue Book, a variety of web-based price information sources, newspaper ads for used cars, and used car dealers. Consumers make such purchases infrequently and carefully, given that such a purchase is usually a relatively large expenditure to the consumer. They usually research alternative costs and shop dealers against one another. In all three of these markets, buyers shop for themselves on the basis of price. In one of the markets, resale markets exist. Since sellers compete on the basis of price, they must communicate price to consumers, and in that case the buyers do not need to know the seller's acquisition costs, only the price at which the seller offers the product. This is competitive market reasoning, and is correct in that context. Competition among sellers should drive prices down to long-run average costs.

27. This reasoning **is not correct** in bargaining models, which better describe the relationship between payors and physicians in the markets at issue here. The shopping that

[31] Moreover, central features of the pharmaceutical market are ignored by these simple and incorrect analogies. Two of these missing features are the principle-agent problem and the presence of insurance, both of which I discussed in my Declarations in Support of Class Certification (September 3, 2004 and December 16, 2004).

occurs among providers and payors involves RFPs (Request for Proposal) and negotiations subsequent to receipt of proposals. There is no resale market to provide price information, since resale of drugs is against the law.[32] The reimbursement rate formulae that are negotiated will be computerized into relevant reimbursement data bases and will be used to determine the reimbursement rates for a substantial number of claims (from thousands to millions) submitted by the provider over time for a variety of services, drugs and durable medical equipment.

It is well known that in a bargaining context, the information available to both parties affects the outcome of bargaining, including its efficiency properties.[33] When HCFA/CMS and/or TPPs negotiate with providers, information (and in the absence of accurate information, **expectations about such information**) concerning the actual spreads between AWPs and provider acquisition costs determine the negotiating positions taken by both parties. These expectations inform beliefs about the "reservation drug price" or "reservation drug cost" to which TPPs can push providers during the negotiation. When information is asymmetrical, the party with less information and incorrect expectations is unable to strike a "good bargain" or "good negotiation" regarding reimbursement for physician-administered drugs.

That is certainly the case in this litigation: the providers have known the acquisition costs of their drugs; the providers have understood and acted upon the manufacturers' directions to keep secret all information about discounts, free samples and price offsets which determine provider acquisition costs; consequently, payors including Medicare have had incomplete information to effectively negotiate physician-administered drug reimbursement rates reflecting acquisition costs.

[32] The Prescription Drug Marketing Act of 1987 as modified by the Prescription Drug Amendments of 1992 (P. L. 102-353, 106 Stat. 941) on August 26, 1992 forbids such resale.

[33] See Jean Tirole, *The Theory of Industrial Organization*, MIT Press, 1989, pp 22-25.

C. Spread Competition was Practiced by Manufacturers of Single-Source Drugs

28. Reimbursement for Zoladex under Part B is subject to a single J-code and has been based, until 2005, upon the lesser of some percentage of AWP and some measure of provider acquisition cost.[34] As a result, the AWPs and the ASPs for all NDCs of Zoladex were

[34] It is useful to provide a brief summary of statutory provisions determining Medicare reimbursement for Part B drugs by time period.

Prior to 1992:

"Before 1992, Medicare carriers generally paid for drugs based on physicians' estimated costs as measured by the AWP." (Source: Medpac, *Report to Congress: Variation and Innovation in Medicare*, Chapter 9, "Medicare payments for outpatient drugs under Part B," June 2003, pp. 152).

1992 through 1997:

"Payment for a drug … is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. … For multiple-source drugs, payment is based on the lower of the estimated acquisition cost … or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." (Source: 42 CFR 405.517, Revised October 1, 1996).

From 1998 – 2003:

"Payment for a drug or biological … is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological. … For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. (Source: 42 CFR 405.517, Revised October 1, 2003).

For 2004:

"The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA) provides that as of January 1, 2004, the payment limits for drugs and biologicals are based on 85 percent of the April 1, 2003 Average Wholesale Price (AWP), for those drugs and biologicals furnished on and after January 1, 2004. … The Medicare payment limits [%*AWP] for drugs and biologicals not paid on a cost or prospective payment basis, and furnished on or after January 1, 2004, through December 31, 2004, are as described" for a variety of specific Part B medications, including blood clotting factors; new drugs or biologicals (as approved by the FDA subsequent to April 1, 2003); pneumococcal and hepatitis B drugs and biologicals; certain drugs studied by the OIG and GAO; infusion drugs furnished through an item of implanted durable medical equipment; drugs and biologicals not described above. The percentage off AWP for these different medications varies from 80-95%, some based on the April 1, 2003 AWP.

From §20.2: "For a single source drug or biological, the AWP equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of: the median AWP of all generic forms of the drug or biological; or the lowest brand name product AWP." (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 54, December 24, 2003).

vulnerable to strategic manipulation by AstraZeneca. AstraZeneca could inflate the AWPs; reduce the ASPs; or do both, as discussed by the *MedPAC Report* (see footnote 23 above).

D. Examples of the Effects of the AWP Inflation Scheme on the Spreads of Zoladex

29. In this Section, I present price data summarizing the economically motivated pricing strategies of AZ to manipulate the AWP of Zoladex to incentivize providers to move market share, resulting in extraordinary spreads that were certainly not expected or understood by Class members and caused overcharge injury to members of Class 1. Using the data provided by AZ, I have calculated the ASPs by NDC for Zoladex. The difference between AWP and ASP is referred to as the spread.

30. For diagnostic purposes in the remainder of this section, I use the measure of spread calculated simply as (AWP – ASP)/ASP to provide an index of the injury and damages resulting from the AWP Inflation Scheme. Using this measure for Zoladex, I demonstrate the size of the spreads and how the spreads were strategically exploited to compete against its therapeutic substitute, Lupron. While presenting these measures of spreads and the underlying competition, it is useful to keep in mind the preceding discussion that the competition being described is not pro-competitive in the usual sense of the concept, *i.e.*, where price competition reduces consumers prices. In this case, the spread competition was induced by normal competitive impulses for manufacturers to lower prices to gain market share but resulted in increased profits to providers and increased costs to consumers.

From January 1, 2005:

"Per MMA of 2003, beginning l/1/05, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on 106% of the Average Sales Price (ASP). CMS will supply contractors with an ASP drug pricing file for payment of drugs. This pricing file shall be provided to contractors by CMS quarterly. Contractors will continue to price covered drugs not on the file." (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 352, November 3, 2004).

1. Overview – Spread Competition between AZ and TAP

31. Table 1 presents the calculated spreads for a particular NDC of Zoladex for two particular years. For perspective on the spread competition in the market, I include the spreads for several important (by sales volume) NDCs for Lupron, which were subject to the *Lupron Sentencing Memorandum* and TAP's guilty plea. During the Class Period, the courts found that TAP promoted Lupron through illegal sales of free samples, questionable payments, price offsets and other practices all of which were reflected in spread manipulation.[35] TAP pled guilty to the allegations and was fined substantially by the federal government. I performed the analyses in support of class certification and the calculation of damages in the private MDL Lupron litigation. In that analysis, I found that TAP varied the spreads of Lupron NDCs *annually, indeed sometimes quarterly,* to strategically move market share among its alternative NDCs. One strategic desire revealed by TAP was to move the market from its shorter-length presentations to its longer, more costly (three-month and four-month) presentations. To do so, TAP increased the spreads of the presentations for which it sought to increase market share while reducing the spreads for presentations which were no longer being actively promoted.

32. For examples, TAP increased the spread of NDC 00300-3336-01 (Lupron 3-month) from 70.2% in 1996 to 292.1% in 1998. Between 1997 and 2000, TAP reduced the spread of NDC 00300-2440-01 (Lupron Depot-Ped) from 143.1% to 35.7%. By 1998, TAP had increased the spread of NDC 00300-3683-01 (Lupron 4-month) to 301.6%. It reduced this spread to 188.1% by 2000, which was still substantial. In all cases, the federal government found these spreads excessive and the marketing practices creating them illegal.

[35] See *Lupron Sentencing Memorandum.*

Table 1: Illustrative Spreads

Defendant	Drug Name[36]	Spread (Year)	Spread (Year)
AstraZeneca	Zoladex	40.7% (1995)	149.7% (2001)
TAP	Lupron 3-month	70.2% (1996)	292.1% (1998)
TAP	Lupron Depot-Ped	143.1% (1997)	35.7% (2000)
TAP	Lupron 4-month	301.6% (1998)	188.1% (2000)

2. AZ's Strategic Response – Zoladex Spread Inflation

33. AZ responded to TAP's spread inflation of Lupron by inflating the spreads of its NDCs of Zoladex in ways already identified as "egregious" by Dr. Berndt and discussed explicitly by the *MedPAC Report* (see footnote 26 above). Both Zoladex and Lupron are treatments for prostate cancer. Zoladex is a LHRH (luteinizing hormone-releasing hormone) that is therapeutically similar to TAP's Lupron, which was already on the market when AZ launched Zoladex.[37] Both launched prior to 1991, the beginning of the Class Period.

34. In order to compete with Lupron, AZ exploited the same tactics used by TAP for marketing and promoting Zoladex. Indeed, AZ was investigated, sued and forced to enter into a settlement plea agreement, also subject to damages paid to the federal government.[38] The

[36] The spreads for the following drugs have been reported for a specific NDC identified as follows: Zoladex (00310-0960-36); Lupron (00300-3336-01, 00300-2440-01, 00300-3683-01).

[37] Lupron launched in June 1985 and Zoladex launched in January 1990.

[38] See Plaintiffs' Exhibit 3, the Transcript of Hearing, June 20, 2003, *United States of America, Plaintiff v. AstraZeneca Pharmaceuticals LP, Defendant,* in which AZ pled guilty to one count charging it with violation of the Prescription Drug Marketing Act, 21 U.S.C. §§ 353(c), 331(t) and 333(b)(a)(B), by causing the sale of drug samples.

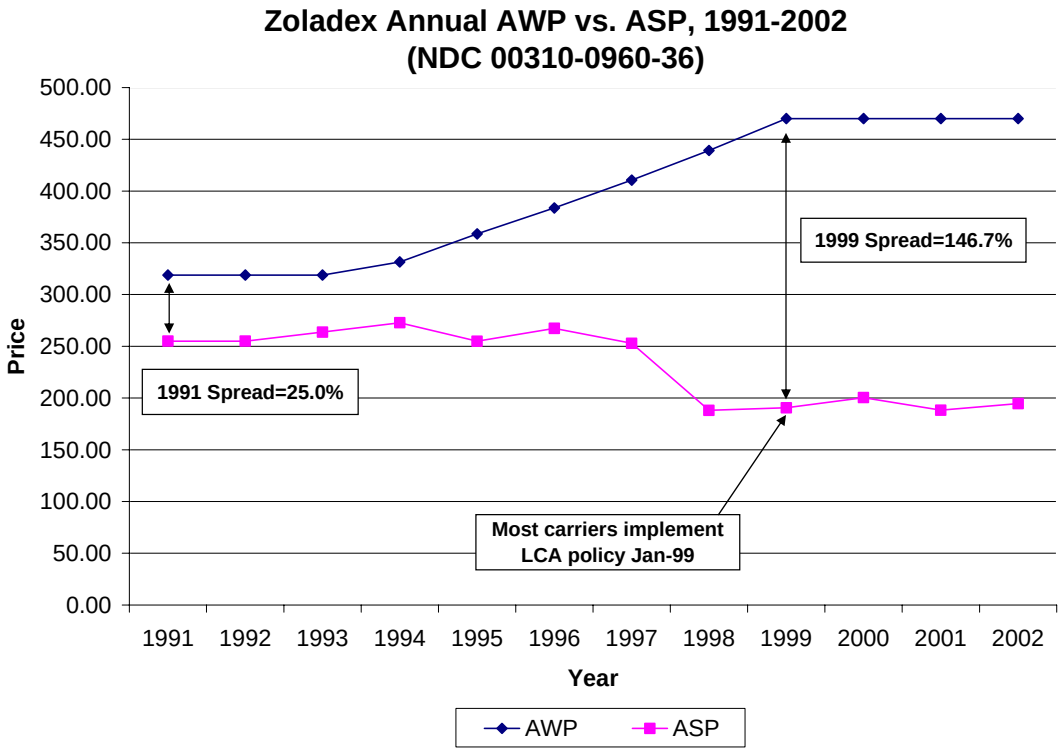
As admitted by AZ's counsel therein (p. 8):

"…Beginning in or about 1993, and continuing at least until July 1996, some Zeneca employees provided free samples of Zoladex to physicians, knowing and expecting that certain of those physicians would prescribe and administer samples to their patients and thereafter seek and receive reimbursement, in violation of the Pharmaceutical Drug Marketing Act.

When this was done, one of the objectives was to induce the physician to order Zoladex. It was an objective of the physicians to bill for the free samples in order to increase their income…."

spreads for the two years presented in Table 1 are 40.7% (1995) and 149.7% (2001). In Figure 1, I chart the spreads annually for the same NDC (00310-0960-36), using the Average Sales Prices (ASP) and AWPs.

Figure 1:



35. Figure 1 demonstrates several important points. From 1991 through 1994, the spread between ASP and AWP remained steady, at or below 25%. Aggressive spread inflation was not pursued by AZ. However, beginning in 1995, AstraZeneca began simultaneously

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Government counsel summarized the case as follows (p. 9):

> "…Beginning in or about 1993 and continuing to at least July 1996, the defendant, which is called Zeneca here, through its employees, provided thousands of free samples of Zoladex to physicians knowing and expecting that certain of those physicians would prescribe and administer those drug samples to their patients and thereafter seek and receive reimbursement for the free samples…."

See also Plaintiffs' Exhibit 1 (*Memorandum of Plea Agreement)* and related litigation, *United States of America v. Robert Berkman*, Criminal Action No. 03-45-JFF (Plaintiffs' Exhibit 5).

lowering the ASP and raising the AWP for Zoladex. The spreads in Figure 1 corroborate AZ's practices designed to compete with Lupron. The fraudulent promotion of selling free samples and other price offsets began in 1993 (see footnote 38). Hence, as noted by *MedPAC* (¶ 21 above), the spread was being increased through the two blades of the scissors – intentional reduction of the ASP (through price offsets and provision of free samples to sell) and intentional inflation of the AWP. These observed spreads are consistent with the theory of competitive spread inflation, through which manufacturers responded to economic incentives by increasing the spread **to the benefit of providers and not to the benefit of either consumers or payors.** I note that the increase in the AWP for this NDC of Zoladex ends in 1999, at which time the majority of state Medicare Part B carriers had adopted a Least Costly Alternative (LCA) policy whereby reimbursement for Lupron and Zoladex would be reimbursed based on the AWP for the less costly of the two.[39] Since the least costly alternative was (and still is) Zoladex, this meant that any increase in Zoladex's AWP would increase the spread for **both** Lupron and Zoladex, thus eliminating the competitive impetus for AWP manipulation. While inflation of the AWP alone no longer provided incentives to move market share, the spread does not decrease. AZ could still strategically make use of its ASP, lowering it relative to its AWP, in order to effectively compete for market share relative to Lupron. AZ clearly understood these aspects of "Return to Practice" as demonstrated by this 1995 AZ internal memo:

> " ... [T]he Return to Practice that can be realized via the purchase of LHRH agonists is the primary driver behind this market. Return to Practice is enhanced by widening the margin between the published price and the acquisition cost. This can be accomplished through several pricing manipulations:
>
> 1) Increase the AWP

[39] As discussed in footnote 16 above, the LCA policy was adopted by HCFA carriers beginning in May 1997. South Carolina was the first state to adopt it and in time it was adopted by almost all states.

> 2) Decrease the acquisition cost relative to the AWP, or
> 3) Both 1 and 2.
>
> In order to maximize the Return to Practice, and to maximize our competitive position, it is recommended that we exercise option #3 from above by implementing a differential price increase. …. Furthermore, in order to allow Zoladex to be competitive with Lupron in the top tier of accounts, it is recommended that we **create a discounted tier of 24% for purchases in excess of 192 depots (32 cases).** The net result of these two pricing actions is that purchases of Zoladex will result in a **more favorable Return to Practice than Lupron at all purchase volumes** above 6 depots."[40]

36. AZ documents produced in discovery are substantial and confirm my opinion that AZ manipulated the AWP and/or the ASP to compete for market share with TAP's Lupron as TAP manipulated the spread.

a) AZ explicitly recognized that Zoladex's market share and profitability would be increased through spread manipulation:

- "The market we are in wants a more expensive Zoladex, because the doctor can make more money."[41]
- "During 1996, the basic strategies that guided our promotional efforts for Zoladex included: 1) presentation of an improved economic profile to the direct purchasing urologist."[42]

b) One memo explained, "Return to Practice" was essential in order to compete:

> "ZENECA has learned that in order to compete in [the] market dominated by Medicare, there needs to be a compelling argument based on 'total Return To Practice.' It is on this basis that many Urologists decide which LhRh agonist to use. … Return To Practice is derived by adding the difference between Medicare reimbursement [based on AWP] and acquisition price, … patient co-

[40] Internal Memorandum from Keith Patterson to Chris Iacono, November 20, 1995 regarding Zoladex Pricing Strategy, Plaintiffs' Exhibit 118 (AZ0080407-11 at AZ0080409).

[41] See Plaintiffs' Exhibit 117 (AZ0021838), October 12, 1995 Memo from Thomas Chen to Keith Patterson re: Price Increase for Zoladex.

[42] Plaintiffs' Exhibit 69 (AZ0004616-38 at AZ0004633), Zoladex Strategic Summary 1998-2002."

pay which equals the 20% deductible that Medicare does not pay, and the benefit of [certain volume discounts]."[43]

Deposition testimony further confirms that AZ used return to practice as one of its marketing strategies.[44]

c) On November 3, 1995, AZ's Market Strategy & Contract Operations and the Zoladex Marketing Team recommended an 8.25% increase in AWP to create a 30% spread, "which leverages reimbursement" and "deliver[s] a per-unit Return To Practice in excess of what Lupron's current scheme can deliver."[45] The memo further recognized that AZ needed a compelling spread:

"Our campaigns to grow ZOLADEX sales based on product attributes and somewhat straightforward pricing strategies have continually been thwarted by TAP responses as well as the method used by Medicare to reimburse for LhRh agonists. Without rehashing the entire economic scenario, ZENECA has learned that in order to compete in market dominated by Medicare, there needs to be a compelling argument based on 'total return to practice.'"[46]

[43] Plaintiffs' Exhibit 14 (AZ0237142-163, at AZ0237143), November 3, 1995 Memo from Market Strategy and Contract Operations and the Zoladex Marketing Team. The definition of Return to Practice as the spread between AWP and the actual acquisition cost to physicians is also confirmed in AZ deposition testimony (see Deposition of Christopher Waldo Bowman, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS, October 13, 2005, pp. 37-38 and Deposition of Steven Strand, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS, June 17, 2005, p. 66).

[44] "Q. And so just to clear that up, you do agree that Zeneca did use return to practice as one of its marketing strategies with respect to Zoladex; is that right? A. Yes." (Deposition of Thomas Chen, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS, December 14, 2005, p. 126).

"Q. At your initiative, did you ever discuss return with doctors during that time period [mid-90s]? A. I would imagine, I think it opened some doors for us when we had a new pricing structure. It was something that we can kind of go in and discuss with doctors on the pricing of Zoladex, so, yes." (Bowman Deposition, p. 44.)

"Q. And so after '98, you would still use the return to practice as one of the arguments for why a physician should purchase Zoladex as opposed to Lupron; is that right? A. Yes. Q. Did you ever stop using the return to practice as one of those arguments at any time? A. No." (Bowman Deposition, pp. 102-103.)

[45] Plaintiffs' Exhibit 14 (at AZ0237144), *op. cit.*. S*ee also* Chen Deposition (pp. 102-105). Even though it appears that this proposal was not accepted or enacted, it shows that AZ was exploring a variety of ways of increasing the spread.

[46] Plaintiffs' Exhibit 14, *op. cit.* (at AZ0237143).

d) This memo is part of a longer market strategy document emphasizing the profit motive incentivizing urologist/oncologist providers, which Zoladex sales representatives would review with urologists to increase sales of Zoladex by showing the doctors "how much money the doctor or the office could save by purchasing one drug over the other."[47]

> "Market research as well as anecdotal trade reports are replete with mentions of Urology Networks forming in the marketplace. Physicians are banding together across states in order to vie for third party pay contracts as well as fend-off managed care attempts to force them to enter into deep discount agreements for patient care. As we have come to understand in our experience with ZOLADEX, Urologists are motivated by economics. Perhaps more so than any other medical specialty we have encountered. The higher volume discount now being offered by TAP positions Lupron as delivering a higher return to practice within these newly forming groups. Our campaigns to grow ZOLADEX sales based on product attributes and somewhat straightforward pricing strategies have continually been thwarted by TAP responses as well as the method used by Medicare to reimburse for LhRh agonists. **Without rehashing the entire economic scenario, ZENECA has learned that in order to compete in market dominated by Medicare, there needs to be a compelling argument based on 'total return to practice'.** It is on this basis that many Urologists decide which LhRh agonists to use"[48] (emphasis added).

e) AZ created Physician Buy Groups that could take advantage of higher volume discounts to create higher spreads and profits for Zoladex purchasers. Initially, purchase groups were informal associations of urologists. As time went by, Buy Groups became part of AZ's contract strategy, and members formally contracted with AZ.[49] It was these Buy Groups that were

[47] Bowman Deposition, pp. 56-58.

[48] Plaintiffs Exhibit 14, *op. cit.* (AZ0237142-163 at AZ0237143).

[49] Bowman Deposition, pp. 45-46, 70-71, 73.

contractually required to maintain confidentiality[50] regarding price competition between TAP and AZ, as discussed in my ¶ 25.b) above.

f) AZ understood what the AWP/ASP spread and Return to Practice meant and how it could be used to compete with Lupron.

"The single most important force behind the popularity of the LHRH agonists is their profitability, which is a direct result of Medicare reimbursement policy."[51]

"TAP has grown Lupron sales to approximately $650 million with 80 percent to 90 percent of sales being in the prostate cancer market. They have achieved this goal through aggressive promotion that emphasized the profit potential from Medicare reimbursement. Medicare reimburses LHRH Analogs at Average Wholesale Price (AWP) minus 20 percent. Lupron has a higher AWP than Zoladex, therefore, the physicians have made greater profit margins for injecting Lupron than Zoladex. Commercial intelligence reports that TAP offer various incentive programs that enhances the profit potential for the physicians. The profit motive of the physicians has made it very difficult for Zeneca to compete effectively in this marketplace. The transition of Medicare patients into managed care will be a positive benefit for Zoladex as 'cost' instead of 'profit' will be of greater concern in this market. TAP will not relinquish this business easily, therefore, Zenaca will be forced to discount the price of Zoladex to fend off TAP."[52]

A Zoladex contracting strategy document shows that AZ recognized what return to practice is, they calculate return to practice and compare to Lupron (at AZ0427252-3). In addition, "'Return to practice' favors ZOLADEX with most important customers"[53]

"[…] we have recently learned of a TAP 'bounty' program, whereby the TAP representatives were empowered to offer unrestricted grants (as high as

[50] See Plaintiffs' Exhibit 244, *op. cit.*

[51] See Plaintiffs' Exhibit 105 (AZ0004734-55 at AZ 0004746) "Zoladex Strategic Plan, 1996-2000."

[52] See Plaintiffs' Exhibit 245 (AZ0022281-94 at AZ0022288) "Medicare Market Segment Strategic Plan, 1997-2001."

[53] See Plaintiffs' Exhibit 139 (AZ0427246-65 at AZ0427264) "Proposed Zoladex Contracting Strategy."

> $10,000) to any account who had converted to Zoladex 10.8mg in return for switching back to Lupron 3-month depot."[54]
>
> "Some non-users use Lupron because profit obtained from Medicare reimbursement is greater for Lupron than ZOLADEX."[55]
>
> "Medicare reimbursement for LHRH injections allows urologists to make additional profits. TAP has capitalized on this situation by promoting Lupron's profit potential."[56]

g) It is my understanding that the methods to reduce ASP identified above would violate the False Claims Act and the federal antikickback statute, as described by the *OIG Compliance Program Guidance.*

IV. THE CALCULATION OF DAMAGES FOR CLASS 1

A. Overview

37. I understand the Court has adopted the "plain meaning rule," and that published AWPs and the Medicare reimbursement rates derived from those AWPs were to be reported in accordance with either the *OIG Compliance Program Guidance* or with the *MPDIMA* guidelines, or with the application of the principles found in these two sources for the calculation of the drug acquisition costs of providers. I have been instructed by Counsel to proceed with this understanding. I assume that the "plain meaning rule" will require application of either set of guidelines in order to estimate the average drug acquisition cost of providers. Taking that interpretation as my point of departure, it is my opinion that the published AWPs, or the relevant percentages of those AWPs (95% and 80%, in accordance with footnote 34 above) for Zoladex did not meet that "plain meaning rule" when reimbursement rates calculated according to the

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[54] See Plaintiffs' Exhibit 142 (AZ0004662-84, AZ0428340) "Zoladex Strategic Summary 1998-2002".

[55] See Plaintiffs' Exhibit 246 (AZ0092152-62, at AZ0092153) "Prostate Cancer Situation Analysis Review."

[56] *Ibid*. at AZ0092154.

Medicare statutes exceeded the ASP. Under the "plain meaning rule," I understand that if this difference is positive, injury has been demonstrated and the extent of the damages quantified.

38. If AWP was to be a published price that reflected all discounts, rebates and price offsets offered by a manufacturer to all non-governmental entities (*i.e.*, AWP was to conform to the *OIG Compliance Program Guidance* or the *MPDIMA*), the reported AWP would be (approximately) the ASP on all units sold ***to all non-governmental entities***.[57] Alternatively, if the Court defines AWP to be a published price that reflected all discounts, rebates and price offsets offered by a manufacturer to providers of the physician-administered drug (*i.e.*, AWP was to conform to the *OIG Compliance Program Guidance* and the *MPDIMA* for all units sold to the relevant providers), the reported AWP would be (approximately) the ASP on all units sold ***to all relevant providers.***[58] In either case, the injury to members of Class 1 is determined formulaically as the difference between the reimbursement rate based upon some percentage of the published AWP (as determined in footnote 34 above) and the relevant ASP. However, for my analysis I have interpreted the "plain meaning" rule with somewhat greater nuance, which I clarify through a discussion of reimbursement for single-source drugs.

a) Over the period 1991 through 1997, 100% of AWP was the basis for reimbursement of single-source physician-administered drugs. By the "plain meaning rule," therefore, the AWP should have been a reliable measure of the average acquisition cost of providers, *i.e.*, the providers' ASP, taking into account all price offsets

[57] My reading of the recent *MPDIMA* suggests that CMS defines ASP in this fashion; see footnote 3.

[58] This definition of ASP would accord most closely with the notion of cost-based reimbursement under Medicare, since this measure of ASP would reflect the acquisition costs of providers, rather than the overall average acquisition costs of all users. This definition makes most sense as a matter of economics. Use of this definition of ASP **will produce the smaller measure of damages,** since ASPs calculated under this definition will be higher than under the one for all users. For my analysis here, I make use of the ASP as it relates to providers as the "plain meaning rule."

clarified by *OIG Compliance Program Guidelines*. To the extent that AWP exceeded the ASP, by the "plain meaning rule," payments by Medicare beneficiaries were too high, on average, and Class members were impacted and injured, on average, for all claims reimbursed.

b) Over the period 1998 through 2003, 95% of AWP was the basis for reimbursement of single-source physician-administered drugs. By extension of the "plain meaning rule," I assume that 95% of AWP should have been a reliable measure of the average acquisition cost of providers, *i.e.*, the providers' ASP, taking into account all price offsets clarified by *OIG Compliance Program Guidelines*. To the extent that 95%*AWP exceeded the ASP, by my extension of the "plain meaning rule," payments by Medicare beneficiaries were too high, on average, and Class members were impacted and injured, on average, for all claims reimbursed.

c) During the year 2004 in which CMS transitioned to ASP-based reimbursement, x% of AWP was the basis for reimbursement of single-source physician-administered drugs, where x% is determined by the specific drug (it ranges from 80%-95%, with the majority being 85%; see footnote 34. It was set at 80% for Zoladex). Again, by extension of the "plain meaning rule," I assume that x% of AWP should have been a reliable measure of the average acquisition cost of providers, *i.e.*, the providers' ASP, taking into account all price offsets clarified by *OIG Compliance Program Guidelines*. To the extent that x%*AWP exceeded the ASP, by my extension of the "plain meaning rule," payments by Medicare beneficiaries were too high, on average,

and Class members were impacted and injured, on average, for all claims reimbursed.[59]

B. Formulaic Methodology for Calculating Damages

39. As the Court states, for Medicare Part B drugs "the reimbursement rate is set by statute, not negotiation," … and "damages calculations will be largely formulaic."

40. More specifically, for single-source brand name drugs reimbursed by members of Class 1,

a) Prior to 1992, Medicare carriers took the AWP to be the physicians' estimated acquisition cost and reimbursed at AWP.

b) From 1992 to 1997, reimbursement was set at the lesser of the estimated acquisition cost ("EAC") or AWP.

c) On January 1, 1998, reimbursement was changed to the lesser of (1) the billed charge on the Medicare claim form or (2) 95% of AWP. This practice continued through 2003. While the statutory language changed to the "lesser of the billed charge" or 95% of the AWP, the understanding of "the billed charge" was the EAC of the drug, despite the fact that 95% of AWP was used systematically to determine reimbursement.[60]

[59] I note in passing that in all cases this interpretation of the "plain meaning rule" is that in the but-for world, Medicare was to reimburse at the average acquisition cost of the drugs (to the providers). Had the AWP been equal to and continued to have been equal to the "weighted average wholesale price (or acquisition cost)" to providers (as asserted by the FDB in their promotional materials), there would have been no need for Congress to reduce the reimbursement rate to 95% or 85% of AWP. The reduction to 95% and 85% reflects the growing awareness by Congress that the "plain meaning rule" was being violated by the drug manufacturers.

[60] See footnote 14 above.

d) From January 1, 2004 through December 31, 2004, drugs were generally reimbursed at 85% of AWP. Zoladex was reimbursed at 80% and other exceptions are clarified in footnote 34.

41. By the "plain meaning rule," I interpret these statutory changes as follows. I understand that the amount allowed for reimbursement was intended to be equal to EAC = ASP over the period 1991-2004. The variation of the amount allowed as reimbursement and its relationship to AWP over time produces the following formulaic measures of Overcharge Damages per unit reimbursed by members of Class 1.

a) For Medicare single-source Part B drugs:

- Overcharge = (AWP – ASP) for 1991-1997;
- Overcharge = (95%*AWP – ASP) for 1998-2003; and
- Overcharge = (x%*AWP – ASP) for 2004, where x% was determined to be 80% for Zoladex, but it was allowed to range from 80%-95%, with the majority being 85%.[61]

I take 20% of the amount of the difference between the amount allowed and the amount that should have been allowed under the "plain meaning rule," since that is the coinsurance covered by the members of Class 1 under Supplemental Medicare Coverage.[62] Note also that in 2005, Congress set reimbursement based upon ASP. I do not calculate damages for Medicare Part B for 2005, since in that year it returned to an explicit cost basis.

[61] Recall from footnote 34 that the relevant AWPs and ASPs for the 2004 calculation are those of April 1, 2003. Multi-source drugs require a different but still formulaic calculation, which is unnecessary given the fact that Zoladex was single-source throughout the Class Period.

[62] The 20% Medicare coinsurance generally is paid by one of three groups of payers: out-of-pocket Medicare beneficiaries (Class 1), Medicaid (excluded from my analysis) and private third-party payers (Class 2). According to Eppig and Chulis, out-of-pocket Medicare beneficiaries account for 13.8% of the Medicare coinsurance payments; see F. J. Eppig and G. S. Chulis, "Trends in Medicare Supplementary Insurance: 1992-1996, *Health Care Financing Review*, Vol. 19(1), Fall 1997.

42. The units subject to reimbursement need to be calculated. I discuss how this calculation is performed in Section VI.B below, which addresses technical issues. Likewise, reimbursement rates are calculated by NDC.

C. The Damage Calculations

43. I have calculated the ASPs to providers and gathered data on the AWPs required to determine damages. I calculate damages as x*AWP – ASP for Class 1 (where x represents the percentage discount off of AWP as described above). The aggregate Class-wide damages are summarized below in Table 2. The back-up for Table 2 is provided in Attachment F.1.

I have also been asked by Counsel to calculate an alternative measure of damages as a sensitivity analysis. Specifically, I have been asked to assume that under the "plain meaning rule," reimbursement should have been based upon the cost-based rate implemented by the MPDIMA, that is, 1.06*ASP. In this case, I calculate damages as x*AWP – 1.06*ASP for Class 1. The results of this sensitivity analysis also are presented in Table 2 with the back up provided in Attachment F.2.

Table 2: Summary of Class 1 Damages Calculations

Calculation		Total Nominal Damages	Total Damages with Prejudgment Interest
Using "Plain Meaning Rule"			
	Through 2003	$26,306,673	$33,846,863
	Through 2004	$31,128,851	$39,089,780
Using 1.06*ASP			
	Through 2003	$24,914,455	$31,955,616
	Through 2004	$29,544,256	$36,989,372

V. EVOLUTION OF GOVERNMENT KNOWLEDGE AND EXPECTATIONS REGARDING AWP AS A RELIABLE SIGNAL FOR COST: WHAT MEDICARE AND MEDICARE BENEFICIARIES KNEW

44. Counsel has instructed me that it is unclear whether the Court will allow testimony concerning government knowledge of the spreads for Zoladex or knowledge of the return to practice marketing activities of AZ. To the extent such evidence is deemed relevant I address this issue here.

45. Much discussion in this matter has addressed what various government agencies knew, when they knew it, how that information was revealed to them, and how they revealed their understanding of that information through observable behavior. It is useful to examine the response of Medicare to evolving information concerning reimbursement for and acquisition cost of physician-administered drugs. Indeed, the responses of HCFA, CMS and the Medicare carriers over time provide a natural experiment for revealing what they believed provider drug acquisition costs systematically were relative to the basis for reimbursement, the AWP.

46. AstraZeneca has argued that HCFA and Medicare knew that AWP exceeded EAC and ASP and that they were aware of survey evidence that AWP exceeded EAC and ASP, at times "substantially." As a result, AstraZeneca has asserted that HCFA and Medicare were not deceived by the particular instances of AstraZeneca's alleged abuse of the AWP system through AWP inflation schemes, and that HCFA and Medicare had the information, ability and duty to mitigate the reimbursement impacts of AstraZeneca's particular abuses of the AWP system.

47. In making these assertions AstraZeneca has appealed to publicly available information developed by the Department of Health and Human Services (DHHS), the Office of the Inspector General (OIG) of DHHS, the General Accounting Office (GAO) and other academic and popular press research. To better understand their information content, I have

compiled a list of these reports. I present that compilation in Attachment D to this testimony and summarize their findings. For my purposes here, note that only a subset of these studies present original survey information.[63] While even other studies could be added to this list, I believe this current list to be sufficiently representative.[64] From reviewing this list I conclude the following:

a) Many (33%) of the OIG studies focus upon self-administered drugs, branded and generic rather than the drug subject to this litigation.[65]

b) Approximately 44% of these studies focus upon physician-administered drugs other than the generic drug albuterol.[66] I relied upon two of them. In an attempt to look at trends over the decade, I identified one study implemented early in the Damage Period (the 1992 OIG report on chemotherapy drugs) and one study undertaken late in the damage period (the 2001 ASCO review of spreads on chemotherapy drugs and a prospective analysis of survey methods).[67]

c) For greater thoroughness, I present some survey results within these two end points and after 2001. I find that these additional studies support my findings.[68]

- The Bill Alpert article in Barron's (June 1996), undertakes original research of the top 20 Medicare drugs (in 300 dose forms), many of which were physician-

[63] The other studies make use of data developed in this subset.

[64] I place greater weight on the information content of surveys, rather than newspaper and magazine articles.

[65] Twelve of the 36 studies focused on drugs covered by Medicaid and/or were dispensed through pharmacies; these drugs are for the most part, self-administered.

[66] Sixteen of the 36 studies addressed a variety of Medicare Part B drugs, other than albuterol.

[67] For the full citations of these and other studies referenced in this section, see Attachment D to this Report.

[68] I first introduced these two surveys in my September 3, 2004 Declaration in Support of Class Certification.

administered drugs. Alpert finds spreads for single-source drugs to be 10%-20% below AWP.[69]

- Based on the OIG Report for December 1997, spreads average 18.5% off AWP for 10 single-source physician-administered drugs in 1995. For these same drugs in 1996, spreads averaged 18.9% off AWP for single-source drugs.
- The OIG report from December 2004, "Medicare Payments to Oncologists," calculated payment-to-cost ratios for 16 drugs. Of those 16, 13 were single-source drugs with a weighted average payment-to-cost ratio (spread) of 14%.
- CMS used the Federal Register (Vol. 69, No. 4, page 1085, January 7, 2004) to introduce measures of spreads on single-source and multi-source physician-administered drugs from surveys reported in OIG (2000) and GAO (2001); see Attachment D. The spreads were introduced in support of enacting the *MPDIMA*. The spreads found for single-source drugs (excluding Kytril and Anzemet) were less than 18% and on average the spreads were 16% for single-source drugs.
- Based upon these studies, I conclude that the publicly available survey evidence generally informing the government, policy makers, and industry participants about spreads **on single-source physician-administered drugs** over much of the Damage Period suggested that the spreads were not excessive.

d) Medicare is a large governmental and political organization. While we are focusing on one concern of Medicare, reimbursement for physician-administered drugs, it is a small concern relative to all of the daunting issues that Medicare deals with on a continual basis. The reimbursement for Part B drugs truly falls into the category of

[69] A "spread off AWP" is calculated as (AWP – ASP)/AWP = x. Such as spread is related to my calculation of spread as follows: (AWP – ASP)/ASP = x/(1-x). Hence, if x = 20% = 0.20; (AWP – ASP)/ASP = 25% = 0.25.

"the importance of being unimportant," as designated by the independent expert to this Court on this matter, Professor Berndt.[70]

e) It is analytically unfounded and self-serving to leap from survey information regarding spreads on self-administered generic Medicaid drugs and selected generic physician-administered drugs to all physician-administered drugs reimbursed under Medicare Part B or to a single physician-administered drug, Zoladex. While hindsight, illuminated through discovery in this litigation and other related litigation, demonstrates that the substantial spreads found with generic self-administered drugs and selected generic physician-administered drugs in the latter half of the 1990s were indeed reflected in spreads for physician-administered drugs generally, such a general understanding simply did not exist at that time. No consistent body of survey information supported such a *systematic* understanding, let alone such an understanding with respect to the scheme's impact upon the spreads of single-source physician-administered drugs generally and AZ's Zoladex particularly. Anecdotal information for some individual Part B drugs was not sufficient to change the overall expectation throughout the 1990s that the AWP provided *a reasonable expectation* for

[70] In his analysis of cost cutting efforts by managed care organizations, Dr. Ernst Berndt measures and discusses the extent to which pharmaceutical reimbursements have increased substantially since 1994. The first factor he identifies is "the importance of being unimportant," meaning that despite their significance on an absolute dollar basis, drug reimbursements still accounted for only 5-8% of all health care expenditures. According to Dr. Berndt (p. 102), citing Alfred Marshall, "If spending on some good or service is perceived to be only a small portion of total costs, that good or service will not be as likely to be on cost cutters' radar screens; instead, they will tend to focus more on big-ticket items." As a result, he infers that managed care organizations and payors likely focused their cost cutting efforts and analyses on hospital care, physician services and "all other" categories of reimbursement and expenditure. The lack of focus upon pharmaceutical reimbursement made the fraud alleged in this matter easier to implement and conceal. See Ernst R. Berndt, "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs*, 20(2), 2001.

Note also that Dr. Berndt was analyzing and referring to reimbursement for all drugs in this research, the vast majority of which are self-administered drugs sold at retail. Physician-administered drugs account for a much smaller percentage of total health care expenditure, and therefore are truly "unimportant" to the cost cutters.

the EAC of Part B drugs. Indeed, it is impossible to explain why Medicare, if as well informed as posited by AstraZeneca, would have allowed itself to be economically injured to the extent it was in the Lupron and Zoladex matters[71] and in the case of Vincasar.[72]

f) Reflection on the attributes of an efficient and economically-rational reimbursement system suggests that Medicare would not want to respond in an incremental fashion to specific news about increased spreads for some specific set of physician-administered drugs. Medicare's policy under Part B has been to implement cost-based reimbursement which reflects the relative values and costs of physician services (see the discussion of Medicare's RBRVS system in ¶ 12 above) and the relative costs of drugs (see Attachment C). Under this policy, the amounts allowed for alternative physician-administered drug therapies have been related to Medicare's understanding of their costs (i.e., their AWPs) by some fixed and common percentage. If Medicare were to respond immediately to "new information" about inflated spreads for one or a small set of drugs, that response would come at large administrative costs. For example, CMS could have decided to decrease the payment for Part B physician-administered drugs overall by decreasing the portion of AWP paid (say by decreasing it from 95% to 85%). However, this strategy would have led to unintended decreases in the payments for other drugs not subject to a manufacturer scheme to elevate spreads. If, instead, CMS implemented a payment policy for the physician-administered drugs at issue here that was separate from other physician-administered

[71] See *Lupron Sentencing Memorandum*, *op. cit.*. See also ¶¶ 22-23 above.

[72] See ¶ 21 above.

drugs, two new reimbursement systems would need to have been developed and put into place. Either of these policy choices would have been quite costly to CMS, explaining why information on excessive spreads would have to be "egregious and systematic" (Dr. Berndt's characterization) before it would make sense for a large agency to reform its basic payment practices.

g) Likewise, there were isolated attempts to inform HCFA and Medicare of the AWP inflation scheme. For example, a letter from Ven-A-Care to Dr. Bruce Vladeck of HCFA dated October 2, 1996 alerted HCFA as follows:[73]

- "AWP has become the benchmark in the industry for establishing pharmaceutical reimbursement. … Unfortunately, the pharmaceutical manufacturers have circumvented the intent of the government's reimbursement methodology by falsely reporting inflated AWP pricing information enabling providers to reap windfall profits from the provision of infusion and respiratory drugs." (at p. 3)
- "The manufacturers are and have been reporting false and fraudulent drug pricing information, including a drug's AWP, direct price, "DP", and wholesaler acquisition cost, "WAC" … By falsely inflating drug pricing information, the drug manufacturers increase the profit margins enjoyed by their customers, thereby driving demand upward and increasing utilization." (at p. 4)
- "Seizing the opportunity to exploit their control over drug prices, the drug manufacturers have in some instances, reported higher prices for generic products than the equivalent brand." (at p. 4)
- "The drug manufacturers are further exploiting their ability to falsify pricing information by using their falsifications of AWP as a marketing tool. … Our company has been solicited on numerous occasions by drug manufacturers who brag about their use of falsely inflated pricing information as a reason for purchasing their product over a competitor's with a lower AWP." (at p. 5)

[73] Letter from Z. Bently, Ven-A-Care to Dr. Bruce Vladeck, HCFA, dated October 2, 1996 in re Excessive Reimbursements for Certain Pharmaceuticals by the Medicare and Medicaid Programs. Also marked as Exhibit 34 to my deposition in this matter, February 27, 2006 and Exhibit L to Steven Edwards Declaration filed with the *BMS Motion for Summary Judgment*, March 15, 2006.

- "We understand that the HCFA may be examining a plan that would, for Medicare only, abandon the AWP reimbursement methodology. … this approach is based on the erroneous assumption that there is something wrong with the historical concept of AWP. The damage to the Medicare and Medicaid programs is being caused by false pricing information being submitted by the drug manufacturers rather than truthful representations of AWP. … any plan must insure that there is truth and honesty in drug pricing information provided by the manufacturers and upon which reimbursement decisions are based." (at p. 5)

h) Reliance on such discovery materials as demonstration that HCFA and Medicare were not deceived by the alleged AWP inflation scheme misses the point. The fact is that institutional knowledge is slow to be disseminated, institutionally assimilated and, for good reason (as discussed in ¶ 47.f) above), slow to be acted upon. In the mid to late 1990s, HCFA, CMS and Medicare carriers were becoming aware of **instances** where "the drug manufacturers are further exploiting their ability to falsify pricing information by using their falsifications of AWP as a marketing tool." (as cited in ¶ 47.g), immediately above). Over the same period, HCFA and CMS were becoming aware of **instances** of large, indeed sometimes substantially large, spreads for multi-source physician-administered drugs. However, the evidence that I find publicly available to inform HCFA, CMS and Medicare carriers regarding how far AWP had come to deviate from the reliable cost-based signal that it had been through the 1980s are sporadic, idiosyncratic, and *certainly not systematic*. The evidence certainly was not overwhelmingly sufficient to support restructuring Medicare's reimbursement practices and procedures. It was the slowness of Medicare and HCFA to fully understand the existence and the extent of the existence of the AWP inflation scheme, to understand the economic injury induced by the scheme and to act upon that

understanding, which was exploited by AstraZeneca through the AWP inflation scheme.

48. However, CMS, Medicare and Medicaid did continue to evaluate pricing information for a growing number of drugs revealing increasingly large spreads, leading to a growing awareness of the injury to payors systematically induced by AWP-based reimbursement procedures. By 2003, CMS was able to finally statutorily formalize the growing awareness of the abuse of AWP-based reimbursement through the 2003 *MPDIMA* for physician-administered drugs. Note that while CMS thereby returned Medicare reimbursement to a cost-based system in 2003, it allowed for institutional inertia by moving to 85% of AWP in the transition year (2004) and finally to ASP in 2005. The *OIG Compliance Program Guidance* put in place analogous practices and procedures for reimbursement of self-administered drugs in May 2003. Note that in both cases, manufacturers are now required to provide sufficient information for consumers and payors to understand the acquisition cost for which AWP has been the list price.[74]

[74] For example, according to the OIG *Compliance Program Guidance* at pages 23733-37:

"Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. …

Where appropriate, manufacturers' reported prices [therefore] should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products. … Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements. …

The 'spread' is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the 'spread', it controls its customer's profit.

49. According to AstraZeneca's theory of competitive markets, this slowly-accumulating information, revealed incrementally over time through these sources (surveys, the public press and inside whistle-blowers) should have been immediately and systematically incorporated into Medicare's reimbursement practices and procedures in a fashion not unlike the immediate incorporation of information by the stock market. Any applied economist, focusing upon the practices and procedures of institutions in markets, understands that application of the neoclassical competitive paradigm in that way is naïve. This is certainly true for the markets at issue here.

50. Indeed, one of AstraZeneca's experts, Dr. Daniel McFadden has summarized[75] a body of applied and experimental research explaining why market participants are slow to assimilate and act upon information summarizing possible market changes under conditions of uncertainty and non-transparency. While his discussion focuses upon individuals making

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> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at '95 percent of average wholesale price.' …Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customers from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product."

[75] See Daniel McFadden, "Free Markets and Fettered Consumers," *American Economic Review*, 2006, 96(1), pp. 5-29.

decisions in the health care services delivery market, the conclusions are equally appropriate to institutions.[76] For example, McFadden identifies the following:[77]

a) "[C]onsumers show a reluctance to trade away from any position in which they are established," preferring the current market position and viewing "changes with distaste." Some researchers in this area of rational consumer choice refer to the current market position as the status quo.[78]

b) Institutions monitoring market changes and considering changing operational practices and procedures face costs of adjustment and the risk of being the first-mover, particularly when it requires negotiating terms that no other firm is seeking.[79] **"**The classical idea of herd mentality is that social animals find it easier and more comfortable to adhere to a group, accept group roles, and mimic group behavior than to act independently.**"**

c) "…(O)ur primary source of information on new objects comes from others, through observation, advice, and association. McFadden and Kenneth E. Train (1996) show that in innovation games with uncertain payoff, it may pay to wait, and learn by observing rather than learn by doing."

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[76] For examples of management science research into such institutional inertia see G. Szulanski, (1996), "Exploring internal stickiness: Impediments to the transfer of best practice within the firm," *Strategic Management Journal*, 17, pp. 27-43; and M.T. Hansen, (1999), "The search-transfer problem: The role of weak ties in sharing knowledge across organization subunits," *Administrative Science Quarterly*, 44(1), pp. 82-111.

[77] At pages 12-13; 16, 16, 16, and 12-13 respectively.

[78] The importance of "status quo bias" in preventing consumers from switching to alternative options that would make them better off has been demonstrated by R. Hartman, M. Doane and C.K. Woo (1991), "Consumer Rationality and the Status Quo," *Quarterly Journal of Economics*, Vol. 106, No. 1, pp. 141-162.

[79] Not only do institutions wait to confirm their changing understanding of the shifting competitive terrain, they delay commitment of the economic resources required to accommodate that shifting economic terrain until they are confident of the changes. Without a critical mass of willing participants and substantial capital expenditures, it would have been extremely difficult for Medicare and essentially impossible for any single institutional payor or member of Class 1 to effect any changes on the industry as a whole in order to counteract the AWP scheme.

d) "Charles F. Manski (1991) has explored the possibility that individuals faced with dynamic stochastic decision problems that pose immense computational challenges may simply look to others to infer valuation function to be used to judge the future payoffs of current acts…"

51. I conclude that while sporadic information on increasing spreads for some drugs was incrementally gaining attention by varying entities through varying sources, the principal determiners of reimbursement rates for physician administered drugs, Medicare and Medicare carriers, acted upon this information as institutions and individuals generally do in a variety of similarly complex markets. They revealed status quo bias, slowly realizing the import of the accumulating information until that point was reached where institutionally they acted and revamped their reimbursement procedures to again return reimbursement to the cost-based system Medicare was believed to be. This "slow" response is actually economically rational from the point of view of CMS, as I have explained above. It is corroborated by Dr. Berndt's insights into the "importance of being unimportant."[80] Certainly the behavior of CMS, Medicare and Medicare carriers provide compelling evidence *from a natural experiment of observing large institutions*, limited by bureaucratic practices and procedures, responding under uncertainty to complex information and noisy signals. Those institutions move slowly. This has been my position throughout my testimony to this Court.

52. If AZ and other manufacturers producing single-source physician-administered drugs had set their list prices (AWPs) as accurate signals of the acquisition costs of providers, CMS would not have had to intervene as it did in 2003 with the MPDIMA. Alternatively, if AZ and other manufacturers had truthfully revealed the extent to which the AWP-Inflation Scheme

[80] See footnote 70 above.

was being used to inflate reimbursements rates paid by Medicare and members of Class 1, CMS could have intervened earlier.

VI. ADDITIONAL TECHNICAL AND DATA ISSUES

A. The Use of J-Codes Does Not Interfere with Accurate Calculation of Aggregate Class-Wide Damages

53. Several technical issues arise in the calculation of aggregate class-wide damages, the discussion of which I have postponed until now, for ease of exposition.

54. It is well known that reimbursement for physician-administered drugs relies upon J-Codes, which have been argued by manufacturers make calculation of damages difficult. Indeed, both Judge Saris and Dr. Berndt[81] have noted that the use of J-Codes for invoicing physician-administered drugs under medical benefit claims has obfuscated the reimbursement process; made drug prices much less transparent and difficult to monitor; and has created "opportunities for mischief and abuse" which have been the impetus for this litigation and have resulted "in the egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians."[82] I agree, as I have developed above.

55. Furthermore, this Court has articulated concern that the complexity of the J-Code system, which arguably has facilitated the AWP pricing scheme, may simultaneously make it

[81] In his Report, Dr. Berndt concludes at ¶186, "In the market environment for physician-administered drugs, a variety of forces -- the relatively small dollar amounts they involve, the ambiguity of whether the claims stem from the medical or drug component of the health benefit, the troublesome relationships with providers who act as both buyers and sellers (and prescribers and dispensers) of physician-administered drugs, and the J-code claims system that has obfuscated the utilization and pricing of individual drug products and confounded close monitoring – have together contributed instead to a system lacking checks and balances and inviting abuse. Some of that abuse has already been uncovered in this Court and elsewhere."

[82] At ¶199, ¶204 of Dr. Berndt's Report.

difficult or impossible to accurately calculate the economic injury in the form of damages resulting from the scheme.[83]

56. While it would be unfortunate indeed that one of the devices by which AstraZeneca effectuated its fraudulent pricing scheme and thereby injured consumers would ultimately be the device behind which AstraZeneca could hide from prosecution and payment of compensable damages for that injury, the situation is neither as dire as Mr. Young asserts[84] nor as uncertain as Dr. Berndt suggests.[85] The use of J-Codes for invoicing payors for physician-administered drugs can be readily accommodated by my formulaic damage methodology.

57. I have addressed this issue in some detail with analyses of claims data for private-sector payors (TPPs) and demonstrated that the use of J-Codes does not interfere with my calculation of damages for those payors.[86]

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[83] Specifically, the Court has stated (at pp. 69-70)

"[T]he independent expert, Berndt, expresses concern with Hartman's analysis because of the poor quality of the data available. He cites 'accounting ambiguities' concerning whether physician-administered drugs were covered as medical or drug benefits and a J-Code classification system that 'obfuscated true transaction prices and utilization' in concluding that 'the quality of general information concerning actual prices for physician-administered services is likely to have been very poor.' (Berndt ¶ 228.) He also points out that the 'high touch, high cost' characteristics of physician administered drugs imply that the statistical variance from any sample of information could be 'very high.' (Berndt ¶ 229.) To exacerbate the difficulties in deciphering the data, the literature in the public domain is not helpful in the area of generic drugs administered by physicians. (Berndt ¶ 229.) In a follow-up memorandum, Dr. Berndt states that he expects that the cross-walking between the five-digit J-Code and the eleven-digit NDC code that will be necessary to track actual physician administered drug utilization and unit prices 'is more likely to be feasible and reliable for the more recently introduced and typically more expensive biotech physician-administered drugs, and much less likely to be feasible and reliable for older, and in particular, multi-source off-patent and generic products.' (Berndt Mem. of Aug. 9, 2005 at 2.) He adds that cross-walking will be less feasible for reimbursements made prior to 2000. (*Id.*)"

[84] At ¶ 142 of his Rebuttal Declaration, Mr. Young states "The [commercial payor] reimbursement data [for physician administered drugs] also show that a significant volume of transactions do not occur at a constant relationship to AWP." (See his Exhibit 15.)

[85] At ¶ 197 of his Report, Dr. Berndt states, "This raises the issue of how easy and reliable it is to crosswalk from J-code to NDC-code claims. … Just how labor intensive crosswalking will be, and how individualized the process will need to be in order to be reliable, particularly going back in time to the 1990s, is unclear to me at this point. This is an important issue that merits thoughtful and concise clarification by both Plaintiffs' and Defendants' experts."

[86] See my November 1, 2006 Direct Testimony in the AWP-MDL matter, ¶¶172-175.

58. The issue is even less complex for Medicare and CMS, since CMS determines reimbursement procedures and the constituents of the J-Codes. For that reason, it is useful to review a recent Medicare Claims Processing Manual,[87] specifically that chapter relevant to claims calculation and submission (Chapter 17), keeping in mind that reimbursement practices have changed over time. Under Chapter 17 "Crosswalk to Old Manuals," Section 10 "Payment Rules for Drugs and Biologicals" it states

a) "Most drugs furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) for the service with which they are billed. Certain drugs, however, are paid separately. These include chemotherapeutic agents and the supportive and adjunctive drugs used with them, immunosuppressive drugs, orphan drugs, radiopharmaceuticals, and certain other drugs such as those given in the emergency room for heart attacks. The classes of drugs required to have 'pass through' payments made under the Balanced Budget Refinement Act of 1999 (BBRA) have coinsurance amounts that can be less than 20 percent of the Average Wholesale Price (AWP). This is because pass-through amounts, by law, are not subject to coinsurance. The CMS considers the amount of the payment rate that exceeds the estimated acquisition cost of the drug to be the pass-through amount. Thus, the coinsurance is based on a portion of the payment rate, not the full payment rate."

b) "If the dosage given is not a multiple of the Health Insurance Common Procedure Coding System (HCPCS) code [that is, a J-or Q-Code], the provider rounds to the next highest unit in the HCPCS description for the code. If the full dosage provided is less than the dosage for the code specifying the minimum dosage for the drug, the provider reports the code for the minimum dosage amount." In Section 20.2, those drugs reimbursed under a HCPCS or J Code are to be filed using "the unit of measure by which such HCPCS code is defined" which has been called the "Fundamental Billing Unit."[88] In Section 20.5.4, "Find the Strength and Dosage," methods to identify and use the "fundamental billing unit" are provided.

c) "Drugs and biologicals not paid on cost or prospective payment basis have been paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., RedBook, Price Alert, etc.). Examples of drugs that have been paid on this basis include but are not limited to drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors. The Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003

[87] Taken directly from http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp; accessed December, 2005.

[88] For greater discussion of reliance upon the Fundamental Billing Unit, see footnote 59 and ¶¶ 30-31 of my December 16, 2004 Rebuttal Declaration in this matter.

changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. Beginning January 1, 2004, through December 31, 2004, such drugs or biologicals are paid based on various standards specified in the statute, although the default standard is 85 percent of AWP."[89] In Section 20.2, those drugs for which reimbursement claims are submitted and paid that do not rely upon the "fundamental billing unit" are included in the Not otherwise classified (NOC) Drug Pricing File, for which CMS furnishes a NOC SDP file which contains the NDC code and drug name for every NOC drug under the HCPCS Code (J-Code) for which claims are submitted to local carriers; the unit of measure by which such drug is covered; and the Medicare allowed amount.

d) According to Section 20.4, "Calculation of the AWP", "Carriers must ensure that if any NDCs are added or deleted, the formulae are applied appropriately. A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources …"

59. One implication of these statutory codifications for my damage analysis is the following. Some number of total units of Zoladex may have been dispensed through the hospital out-patient setting during some portion of the Class Period, and the coinsurance amounts for those units were submitted for payment by Class members or TPPs. Some portion (20%) of this coinsurance (which should be billed as the actual acquisition cost) could be counted and included as damages. However, note the following:

a) As discussed in Section VI.B below, I exclude from Class damages **all units sold to hospitals**, even if some of those units are dispensed in an out-patient setting and reimbursed in part by Class members. This exclusion applies to those units with coinsurance amounts. My aggregate damages calculations therefore will be conservative for the affected Classes.

b) Reimbursements for these coinsurance amounts would appear in claims data as relatively unpredictable and perhaps seemingly random amounts. It is likely that many of such claims appear in the reimbursement claims data of the commercial

[89] There is some greater refinement of percentages off AWP for certain drugs, but the relationship is always set by the Reference Manual and by statute. See also footnote 34 above.

payors put forward by Dr. Gaier and Mr. Young in their Rebuttal Declarations, which introduce considerable variation which is not relevant to my calculation of damages.[90]

c) Since I exclude these units from the total units subject to my damage analysis, these types of claims are also excluded from the analysis and any analytic difficulties introduced are eliminated.

d) The majority of the remaining claims are determined by the AWP of the NDC administered or the AWP of the multiples of the fundamental billing unit administered.

60. Finally, and importantly, the feasibility of crosswalking J-Codes to NDCs for Class 1 has been examined and clarified more than a decade ago. Specifically, in a May 1996 publication analyzing the appropriateness of 1994 Medicare prescription drug allowances,[91] the OIG undertook an analysis which found the following:

- "Medicare presently pays for most prescription drugs based on the Average Wholesale Price of the drug product" (p. ii).
- "Drugs are billed to the Medicare program based on codes developed by HCFA. These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand or generic version of the drug was administered" (p. ii).
- "The drug code list [that was analyzed] primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive

[90] See Gaier Rebuttal Declaration, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, October 25, 2004. Note also that when commercial payors are reimbursing as supplemental Medicare payors, those reimbursement claims will be 20% of some proportion of AWP (100%, 95% or 80%, depending upon the relevant year of the Class Period). The presence of such claims in commercial payor claims data bases introduces dispersion in claims data, which should not be interpreted as suggesting that claims are unrelated to AWP.

[91] Department of Health and Human Services, Office of Inspector General, "Appropriateness of Medicare Prescription Drug Allowances," May, 1996, OEI-03-95-00420.

drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used for diagnostic imaging" (p. 3).

- [In the analysis,] "we needed to link Medicare's HCPCS codes to NDC codes. This involved matching the drug product and dosage defined by the HCPCS code with the corresponding NDC codes for all available brand and generic versions of the drug" (p. 3). The analysis focused upon 17 HCPCS codes.
- "For 10 of the 17 codes, the process of linking the HCPCS code with corresponding NDC codes was relatively easy to accomplish since the HCPCS codes represented single-source drugs where only one brand name drug was available. For these drugs, we collected NDC codes that matched the drug dosage requirements outlined in the HCPCS code description" (p. 4).
- "For the remaining seven drug codes, we needed to determine all of the versions (both brand and generic) of the drugs produced by different manufacturers that met the HCPCS dosage requirement" (p. 4).

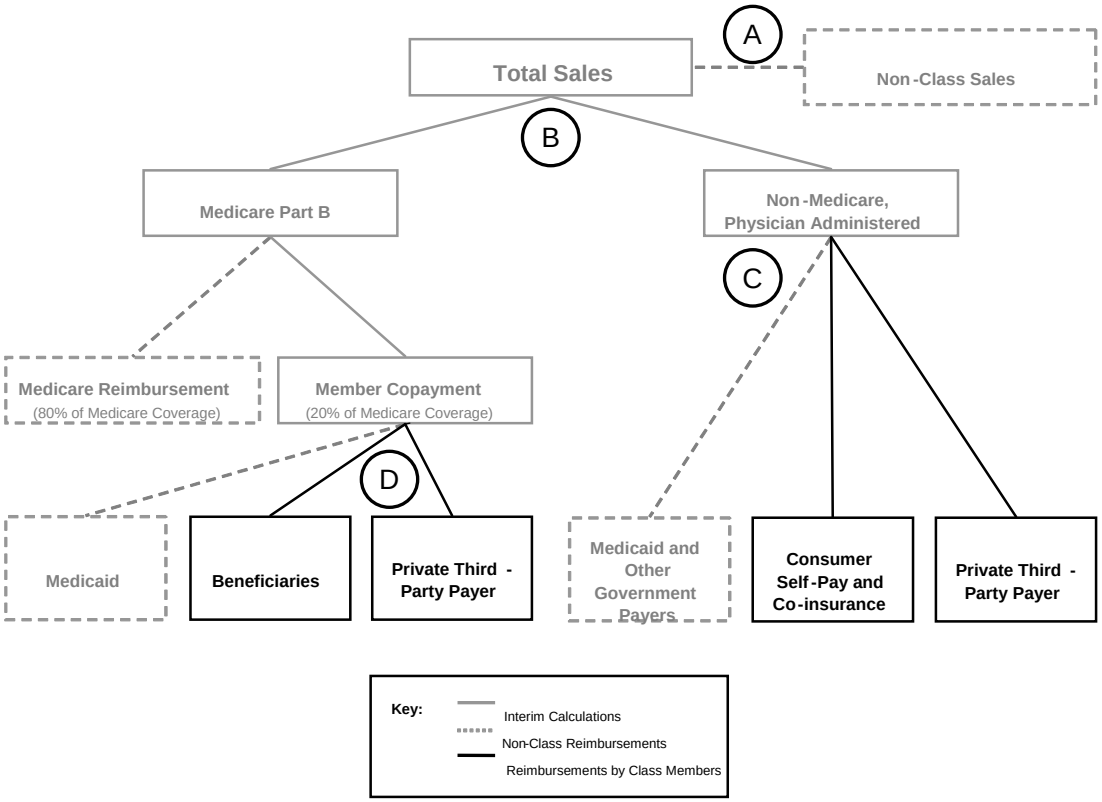
I conclude that the crosswalk from HCPCS Codes to NDC codes was considered "relatively easy" for single-source physician-administered drug reimbursement by Medicare as early as 1994. Since Zoladex is a single-source drug (with only 2 NDCs), J-Code complexity is a non-issue for my calculation of damages.[92] This conclusion is supported by discovery materials and publicly available information I have reviewed.

B. Calculation of the Units Subject to Damages for the Class

61. A schematic diagram of the flow of units to Medicare and non-Medicare payors subject to the damage analysis is presented in Figure 2. There are four important analytic nodes in the Figure, Node A through Node D.

[92] For multi-source drugs, the crosswalk was more data intensive but still possible. It involved identifying all versions, including generic and branded, of the drugs meeting the HCPCS dosage requirement. I know that such a crosswalk is possible, because I have implemented it in other damage calculations. It is not required here.

Figure 2: Schematic of Sales and Reimbursement by Sub-Class



62. At the start of my analysis of liability and damages, I integrate all sales, chargeback and rebate data (provided to date) for Zoladex from AstraZeneca. At the time of the submission of this Report, these data were fairly complete for the years for which the data were received. However, the data were not provided for all years of the Class Period, i.e., they do not extend beyond 2002. I identify where data were not provided and how I accommodated the damage calculations appropriately in the notes to the relevant damage tables in Attachment F. I also identify in Attachment F those states that I have been directed by Counsel are subject to the damage calculations. I reduce total units of Zoladex sold by AZ on an annual basis to reflect the fact that only those sales to these states are subject to damages.

63. Broadly speaking, I use the identifiers for customer name, type, and class of trade to exclude, at Node A, all direct units sold to such entities as hospitals, government entities, managed care dispensaries, and those units distributed through wholesalers which are not later distributed to the physician providers who in turn administer to the Class. Those units not excluded by this process are those distributed to physicians, physician groups, oncology groups, clinics, long-term care facilities, nursing homes and certain others; more details are provided in the notes of Attachment E. When I exclude those units distributed to entities who are not providers to Class members, I also exclude the related chargebacks and rebates. As a result, the ASPs I present in Attachment E are based upon invoiced sales data, price offsets, chargebacks and rebates on units distributed solely to the relevant Class.

64. Having identified those units (and their ASPs) relevant to the Class as a whole, I differentiate, at Node B, those units distributed through providers to Medicare Part B patients and those distributed to non-Medicare patients. This differentiation has been based on survey data summarizing method of payment for procedures at physicians' offices. The two major sources of these data are the National Ambulatory Medical Care Survey (NAMCS) data[93] and the IMS National Disease and Therapeutic Index (NDTI) data.[94] Having differentiated those units that are reimbursed by Medicare Part B as the primary insurer and those that are reimbursed by non-Medicare payors, I calculate, at Node D, the portion of the 20% Medicare copay that is

[93] The National Ambulatory Medical Care Survey (NAMCS) is a widely-used public data set which provides information on the characteristics of the patients (including their insurance) and the providers that use drugs in ambulatory settings. The NAMCS is a national probability sample survey conducted by the Division of Health Care Statistics, National Center for Health Statistics (NCHS), and the Centers for Disease Control and Prevention (CDC). A national sample of office-based physicians provides data on patients' office visits.

[94] The IMS National Disease and Therapeutic Index (NDTI) Data is an office-based survey also summarizing for each physician-administered/Part B drug the method of payment (insurer), the manufacturer, the form (e.g., injectible, tablets, etc.), and the strength (e.g. 15 mg, 30 mg, etc.). I requested and received these data from AZ.

reimbursed by TPPs providing Medicare supplemental insurance and that portion paid by Medicare beneficiaries (i.e., Class 1). I also exclude the portion paid by Medicaid. At Node D, I rely upon existing survey analyses of these payment patterns.[95]

C. Calculation of Damages by NDC is Equivalent to Calculation by Payors through J-Codes

65. I have used manufacturer sales data to calculate overcharge damages, which are incurred by the Class members as a result of inflated reimbursement payments to providers. The question arises: Does the use of manufacturer data provide an accurate calculation of overcharges in payor reimbursements to providers? The answer is yes.

66. For Zoladex, AZ data are delineated by NDC. The damage calculations in Sections IV and VI.A are conducted by NDC and involve only two NDCs, one of which is the fundamental billing unit. The cross-walk to J-Code is totally transparent. Claims for reimbursement are calculated as percentages of the relevant AWP; the but-for AWP is calculated using the relevant ASP.

67. Medicare claims data are delineated by J-Codes. The use of AZ data to measure overcharges at the Medicare claims level therefore assumes the following: first, that providers do submit claims for the physician-administered drugs that they have purchased in the provision of the relevant medical service; second, that the providers are sufficiently profit-maximizing to bill not less than the amount allowed by NDC; third, that providers use NDCs to submit claims to Medicare, principally by reporting the relevant AWPs and units administered (which will be denominated for the actual NDC or the NDC related to the fundamental billing unit); and fourth, that Medicare has reimbursed according to its AWP provisions (footnote 34). The first two

[95] See footnotes 93 and 94 above. NDTI data were used for AZ. The Eppig and Chulis data were also required for this calculation; see footnote 62. For greater specificity, see Attachment F.3.

assumptions are based upon rational economic behavior. I have corroborated the latter two assumptions using claims data and reviewing the relevant public documents (see Section VI.A above).

D. AstraZeneca's CMS Submissions

68. Since sometime in 2004, AstraZeneca began submitting quarterly ASP reports on an NDC basis for each of the drugs involved in this case. These NDC-based ASP submissions to CMS are not publicly available. CMS takes those NDC-based ASP quarterly calculations, converts them to a J-Code ASP based upon weighting of drugs in that J-Code (if there is more than one), multiplies that CMS J-Code ASP by 1.06, and publishes a Medicare Reimbursement Amount for each J-Code. The Medicare Reimbursement Amount is published quarterly based upon the manufacturers' ASP submissions two quarters previously.

69. I understand that Plaintiffs' counsel requested, but were not able to obtain, access to AstraZeneca's calculations of ASPs during the litigation. Accordingly, I did not have access to the methodology by which AstraZeneca applied the CMS regulations to its particular databases to calculate ASPs by NDC. Of course, if I had access to the methodology by which AstraZeneca applied the CMS regulations to the calculation of ASPs (applicable since 2004 to the present), I could apply that methodology retrospectively to the calculation of ASPs during the Class Period (1991-2004).

70. In comparing my estimated ASPs to current CMS ASPs (which are based upon AstraZeneca's submission of NDC-based ASPs), my ASPs are conservative (see Attachment G.2). My ASPs adopt representations made by AstraZeneca regarding application of classes of trade; and provide a "current" ASP as opposed to an ASP that always would be two quarters earlier (hence lower). For these and other reasons, my calculation of ASPs is likely more

conservative than those currently provided to CMS. As a result, my damage calculations are more conservative.[96]

VII. LIMITING REIMBURSEMENT RATES DOES NOT HURT CONSUMERS, IT HELPS THEM

71. Several of AstraZeneca's experts (Drs. McFadden and Gould)[97] have argued imposition of spread threshold would injure consumer interests because manufacturers would respond by increasing ASPs. I disagree and indeed predicted that ASPs would decline in the "but-for" world.[98]

72. Fortunately, we have a natural experiment to test AstraZeneca's theory that ASPs will increase in response to a limitation on the allowable spread. If the analysis of AstraZeneca's experts were correct, when Medicare switched to reimbursement based on the ASP methodology (and restricted reimbursement to be 6% above ASP), all prices would have increased. However, the data demonstrate defendants' experts to be wrong: the following is noted by MedPAC:[99]

> "To demonstrate the effect of pricing changes from 2004 to 2005, we estimated what Medicare would have paid if the volume of all the specific Part B drugs billed in 2004 were paid according to the Medicare payment rates for October 2005. Using this methodology, we calculated that expenditures for all Part B drugs used in 2004 would have cost 22 percent less in 2005."

73. In fact, Medicare reimbursements for drugs in this matter have decreased once better information was available and the AWP Inflation Scheme was no longer supportable.

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[96] Recall that I calculate ASPs to providers rather than to all non-governmental classes of trade; see ¶¶ 37 & 38 above. If the Court concludes that my ASP calculations should more closely follow the CMS approach (and thereby include hospitals as a class of trade for ASP calculations), such calculations could be run.

[97] See Direct Testimony Declaration of Professor John P. Gould, November 10, 2006, ¶45; Declaration of Direct Testimony by Daniel L. McFadden, PhD, pp. 8-9.

[98] See footnote 95 in my December 16, 2004 Rebuttal Declaration.

[99] MedPAC, "Medicare Part B Drugs and Oncology," July 13, 2006, p. 6.

Despite increases in administration and dispensing fees, total reimbursements for drugs have decreased. For example, as I discuss more fully below, the figures in Attachment G.1 demonstrate that total reimbursements for Zoladex have decreased since the inception of the ASP methodology. This fact contradicts AZ's claim that reimbursement rates would rise under any methodology which limited the spread between reimbursements based upon AWP and ASP. This supports my opinion that consumers would have paid less over the Class Period, if they had better information regarding the acquisition costs of AZ's Zoladex and if AZ had published an AWP that reflected all price offsets, including discounts and rebates, as identified above.

VIII. SUMMARY OF CALCULATIONS AND CONCLUSIONS

74. In Attachment E, I summarize those data required from AstraZeneca to inform and calculate damages to the Class caused by AstraZeneca's implementation of the AWP Inflation Scheme.

a) In Attachment E.1.a, I present calculations of the average annual selling prices (ASPs) of all units sold for each of the two NDCs of Zoladex. The ASPs reflect transactions prices to providers specifically,[100] net of all price offsets identified by the MPDIMA and the *OIG Compliance Program Guidance*. Details of the AZ data incorporated into the calculations are presented in Attachment E.2.

b) In Attachment E.1.b, I present data of the relevant AWPs reported by the Red Book, by year.

c) In Attachment E.1.c, I present measures of the spread calculated as set forth in ¶ 30 above; that is, spread = (AWP – ASP)/ASP. While the measure of spread can be

[100] As discussed in ¶¶ 61-64.

calculated in a variety of ways, they all provide comparable measures of AWP inflation. For this measure of spread, the standard relationship between the list price for reimbursement (AWP) and wholesale acquisition (WAC) implies a spread of 20%-25%. Under the "plain meaning rule" put forward by this Court, AWP = ASP and the spread = 0.0%. Under the MPDIMA, reimbursement is set at 1.06*ASP. Taking the "plain meaning rule" to be that AWP is the average wholesale price that allows 6% above ASP, the spread = 6%. Finally, note in Attachment E.1.c that the spreads for Zoladex were 20-25% over 1991-1994. In 1995 the spread increased dramatically above this level.

d) Attachment E.1.d summarizes net sales of Zoladex, by NDC and in total.

75. Attachment F uses these data and presents calculations of damages as follows.

a) Attachment F.1.a presents damages for Class 1 nationally, using the "plain meaning rule" and the resulting spread of 0.0% for a finding of causation and damages. The formula for calculating damages has been put forward in ¶ 41. Damages are presented in nominal dollars and assessing prejudgment interest. Attachment F.1.b shows these damages broken out by Class 1 state. The notes to Attachment F identify the states included and the percentage of total national damages subject to recovery in this litigation. Note that this measure of damages is the measure of Return to Practice for providers.

b) Attachment F.2.a calculates damages if the Court were to rely upon the 6% spread implied by the MPDIMA, both nominal and with pre-judgment interest. Attachment F.2.b shows these damages broken out by Class 1 state.

c) Attachment F.3 provides supporting information regarding the use of NDTI data and other adjustments

76. Attachment G.1 provides more detailed data summarizing changes in overall CMS reimbursement for Zoladex, post implementation of the MPDIMA. As I have stated above, it has been my opinion and my explicit prediction[101] that had AstraZeneca published an AWP that accurately reflected all price offsets (as required of the MPDIMA and the *OIG Compliance Program Guidance*), payments for Zoladex by Class 1 members would have been lower. The data in Attachment G.1 allow me to test this prediction. Specifically, Attachment G.1 documents in detail the changes in Medicare reimbursement for Zoladex from 2002 to 2005, both graphically and using the underlying data. In 2002, Part B reimbursement for Zoladex was $446.49; total reimbursement, including service fees, was $451.56. By 2005, when the 1.06*ASP rule was finally implemented, reimbursement for the drug had dropped to $189.79. The total cost of treatment (the cost of the drug and the cost of the services) dropped from $451.56 to $226.48 in 2005 (including transition fees).[102] The drop in the price of the drug alone was $256.70.

77. Attachment G.2 provides more information regarding Zoladex pricing pre- and post-MPDIMA implementation. Note that the ASP reported by AZ to CMS in 2005 is less than or equal to the range of ASPs calculated in my damage analysis for 2002. From this I conclude the following. First, the ASPs that I have calculated for the purposes of calculating damages are confirmed by AZ's own calculations. Second, my calculations are conservative from the point of view of damage calculations, since they are *greater than or equal* to the AZ calculation in an

[101] See footnote 95 in my December 16, 2004 Rebuttal Declaration.

[102] It was slightly lower excluding transition fees ($225.41; Attachment G.1.d).

earlier year. Given the fact that they are greater means that the calculated spread is lower than it would be if I had used the AZ calculation procedures apparent in their 2005 CMS estimate.

78. I conclude that the formulaic methodology implemented in this Report is based upon sound economic theory and quantitative methods, a valid interpretation of the "plain meaning rule" and a sufficiently complete incorporation of the realities of the business and regulatory practices determining the markets for the administration of and reimbursement for physician-administered drugs.

79. I have implemented my formulaic methodology for the demonstration of causation and liability for Class 1, and having determined liability on an NDC basis annually, I have calculated damages as summarized in Table 2 above.

I declare that the foregoing is true under penalty of perjury.

/s/ Raymond S. Hartman
Raymond S. Hartman

March 16, 2007 Cambridge, MA
Date and Place of Execution

Attachment A

Raymond S. Hartman

Summary of Qualifications

1. My name is Raymond S. Hartman. I am Director and President of Greylock McKinnon Associates (GMA), a consulting and litigation support firm located in Cambridge, Massachusetts.

2. I am an economist specializing in microeconomics, econometrics and the study of industrial organization. Microeconomics is the science used to analyze and characterize the behavior of groups of consumers and producers that constitute markets. Econometrics is a science that makes use of mathematics and statistics to measure and quantify economic behavior and economic phenomena in markets. The study of industrial organization makes use of both microeconomic theory and econometrics. It focuses upon the structure, conduct and performance of the participants (consumers and producing firms) in markets and industries, for the purposes of predicting behavior and addressing such policy issues as antitrust, regulation and industrial policy.

3. I have taught economics, conducted economic research and provided economic consulting in my areas of specialization for thirty years. I taught economics as an Assistant Professor and Associate Professor within the Department of Economics at Boston University over the period 1977-1988. I taught economics as a Visiting Associate Professor and member of the Visiting Faculty at the School of Law, Boalt Hall, University of California at Berkeley over the period 1988-1993. I was a member of the research faculty at MIT over the period 1977-1982, during which time I conducted research in energy markets for the United States Department of Energy. During the same time, I declined the offer of a Visiting Assistant Professorship within the Department of Applied Economics at MIT, and instead lectured on a selective basis. Over the entire period since 1971, I have consulted to federal and state governmental bodies, private corporations, law firms, consulting companies, research organizations and international lending organizations. I have been a research referee for a variety of academic journals. I am the author of more than 100 refereed journal articles, book chapters and research/consulting reports.

4. I have submitted oral and written testimony before federal and state courts of law and regulatory commissions. My testimony as an expert witness has addressed anticompetitive behavior, merger efficiencies, breach of contract, employment discrimination, patent infringement, class certification and the estimation of damages in a variety of markets and industries including, but not limited to, the pharmaceutical industry, the health care services industry, the electric power industry, the banking industry, the agrochemical industry, the copper industry, the defense industry, the cable TV industry, the tobacco industry, the electrical and mechanical carbon products industry, the medical devices industry and the construction industry. I have consulted to counsel on litigation matters in a broader array of markets.

5. I have submitted testimony and/or consulted in litigation requiring the calculation of damages and the evaluation of proposed settlement allocations in a wide variety of matters.

For one set of recent examples, I have submitted such testimony and/or consulted in a variety of health care, pharmaceutical and medical device markets and industries. Working with a team of health care experts, I submitted written testimony assessing and measuring the impacts of smoking on Medicaid health care costs in the Commonwealth of Massachusetts. I submitted testimony analyzing the competitive impacts upon and damages to a class of dental laboratories caused by the restrictive dealer practices of a dominant U.S. manufacturer of medical prostheses – false teeth. I consulted to the group of wholesaler defendants in the Brand-Name Prescription Drugs Antitrust Litigation,[1] addressing issues of wholesaler pricing across classes of trade. I have consulted to counsel to a manufacturer of cardiovascular stents and other related devices in a variety of patent infringement matters, addressing such issues as competition, market penetration of new products and economic damages arising from patent infringement. I have consulted for one group of private plaintiffs in the antitrust matter regarding the prescription drugs lorazepam & clorazepate[2] and for the Federal Trade Commission in the matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P. and Andrx Corporation concerning antitrust claims involving the prescription drug Cardizem CD.[3] My consultation in these two matters addressed such issues as market definition, product competition, class certification and damage estimation. I have consulted to counsel on the matter of damages to the class of direct purchasers of the prescription drug Taxol[4] and on the matter of damages to the class of end-payer purchasers of the prescription drug K-Dur.[5] I have submitted testimony addressing class certification, liability and/or damages for the class of end-payer purchasers in antitrust or RICO litigation concerning the prescription drugs Hytrin,[6] BuSpar,[7] Relafen,[8] Lupron[9] and Cipro in the states of New

[1] *In re Brand-Name Prescription Drugs Antitrust Litigation*, Case No. 94 C 897; MDL No. 997, United States District Court for the Northern District of Illinois.

[2] *In re Lorazepam and Clorazepate Antitrust Litigation*, MDL No. 1290, United States District Court for the District of Columbia.

[3] *In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation*, Docket No. 9293, United States of America Before Federal Trade Commission.

[4] *HIP Health Plan of Florida, Inc., On Behalf of Itself and All Others Similarly Situated v. Bristol-Myers Squibb Co. and American Bioscience*, Case Number 1:01CV01295, United States District Court for the District of Columbia.

[5] *In re K-Dur Antitrust Litigation*, Civil Action No. 01-1652 (JAG), (Consolidated Cases), MDL No. 1419, United States District Court for the District of New Jersey.

[6] *In re Terazosin Hydrochloride Antitrust Litigation*, Case No. 99-MDL-1317 Seitz/Garber, United States District Court for the Southern District of Florida.

[7] *In re Buspirone Antitrust Litigation*, MDL No. 1413, United States District Court for the Southern District of New York.

[8] *In re Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY.

[9] *In re: Lupron Marketing and Sales Practices Litigation*, United States District Court, District of Massachusetts, MDL No. 1430, CA No. 01-CV-10861.

York[10] and California[11] and in the United States.[12] In the MDL AWP litigation,[13] I have submitted testimony in support of the certification of the class of end payer purchasers of the pharmaceutical products produced by AstraZeneca, the Bristol-Myers Squibb Group, the Johnson & Johnson Group, the GlaxoSmithKline Group and the Schering Plough Group that were subject to an alleged scheme to fraudulently inflate their Average Wholesale Price (AWP); I have consulted to the Offices of the Attorneys General for the states of New York and Connecticut in analogous matters. I have submitted testimony supporting the settlement agreements in a variety of these and other pharmaceutical matters.[14]

I have consulted to counsel and/or submitted testimony calculating damages in litigation in other markets, including but not limited to the copper industry, the steel industry, the electric power industry, a variety of labor markets, a variety of spot and futures markets, and a variety of banking and financial markets. I have analyzed these issues in my published research.

6. I received a bachelor's degree in economics (*magna cum laude*) from Princeton University in 1969. I received a master's degree in economics from MIT in 1971 and a Ph.D. in economics from MIT in 1977.

7. My rate of compensation in this matter is $475.00 per hour.

[10] *Anne Cunningham and Norman Mermelstein, Individually and on Behalf of All Others Similarly Situated, v. Bayer AG, Bayer Corporation, Barr Laboratories, Inc., The Rugby Group, Inc., Watson Pharmaceuticals, Inc. and Hoechst Marion Roussel, Inc.*, Index No. 603820-00, Supreme Court of the State of New York, County of New York.

[11] *Cipro Cases I and II*, Judicial Council Coordination Proceeding Nos. 4154 and 4220 (Superior Court, San Diego County).

[12] *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York.

[13] *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court for the District of Massachusetts, MDL, No. 1456, CIVIL ACTION: 01-CV-12257-PBS.

[14] For examples, *In re: Lupron Marketing and Sales Practices Litigation*, United States District Court, District of Massachusetts, MDL No. 1430, CA No. 01-CV-10861; *In re Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY; *HIP Health Plan of Florida, Inc., On Behalf of Itself and All Others Similarly Situated v. Bristol-Myers Squibb Co. and American Bioscience*, Case Number 1:01CV01295, United States District Court for the District of Columbia; *In re Buspirone Antitrust Litigation*, MDL No. 1413, United States District Court for the Southern District of New York; *In re Remeron Antitrust Litigation*, United States District Court, District of New Jersey, Master Docket No. 02-CV-2007.

January 2007

Raymond S. Hartman
Curriculum Vita

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DEGREES

B.A. (MAGNA CUM LAUDE) Princeton University 1969
M.S. Massachusetts Institute of Technology 1971
Ph.D. Massachusetts Institute of Technology 1977

Ph.D. DISSERTATION

An Oligopolistic Pricing Model of the U.S. Copper Industry (MIT, 1977)

HONORS, SCHOLARSHIPS, AND FELLOWSHIPS

1969-71	National Science Foundation Fellowship to MIT
1965-69	Alfred P. Sloan Scholarship to Princeton
1969	Woodrow Wilson Fellowship Honorable Mention
1965	National Merit Scholarship Finalist

RESEARCH AND TEACHING INTERESTS

Econometrics/Statistics
The Economics of Regulated Industries
Energy and Environmental Economics
Microeconomics
Industrial Organization
Law and Economics

POSITIONS

1967-1969	Research Staff, Financial Research Center and Center for Economic Research, Princeton University
1970	Research Staff, Board of Governors, Federal Reserve Board, Washington, DC
1972-1992	Consultant and Staff Economist, Arthur D. Little, Inc.
1977-1984	Research Faculty, Massachusetts Institute of Technology
1977-1983	Assistant Professor, Department of Economics, Boston University
1983-1989	Associate Professor, Department of Economics, Boston University
1983-1988	Principal & Academic Principal, The Analysis Group
1988-1993	Visiting Associate Professor/Visiting Faculty, Boalt School of Law, University of California, Berkeley
1988-1995	Founding Principal, The Law and Economics Consulting Group
1995-1996	Vice President, Charles River Associates
1996-1999	Senior Consultant, Charles River Associates
1996-2000	Director, Cambridge Economics, Inc.
2000-2004	Special Consultant, Lexecon Inc.
1997-	Director and President, Greylock McKinnon Associates

OTHER PROFESSIONAL ACTIVITIES

Research Referee, *Bell/Rand Journal of Economics, Resources Policy, IPC Science and Technology Press, Management Science, Land Economics, Science, Energy Journal, Applied Economics, Econometrica, Review of Economics and Statistics, Journal of Business and Economic Statistics, International Economic Review, Journal of Economics and Management Strategy, Pakistan Journal of Applied Economics, Journal of Health Economics, American Economic Review, Review of Industrial Organization*

PAPERS APPEARING IN OR BEING SUBMITTED FOR PUBLICATION IN REFEREED JOURNALS AND BOOKS

"Frontiers in Energy Demand Modeling," Annual Review of Energy, 4, 1979.

"The Economic Impacts of Environmental Regulations on the US Copper Industry," with K. Bozdogan and R Nadkarni, The Bell Journal of Economics, 10(2), Autumn 1979, pp 589-618.

"Schumpeterian Waves of Innovation and Infrastructure Development in Great Britain and the United States: The Kondratieff Cycle Revisited," with D. Wheeler, Research in Economic History, 1979, Vol 4, Chapter 2.

"U. S. Demand for Copper: An Introduction to Theoretical and Econometric Analysis," with K. Bozdogan, in R. Mikesell, The World Copper Industry, Resources for the Future, 1979, Chapter 5.

"Some Evidence on Differential Inventory Behavior in Competitive and Non-Competitive Market Settings,"

Quarterly Review of Economics and Business, 20(2), Summer 1980, pp. 11-27.

"Short-Run Residential Demand for Fuels: A Disaggregated Approach," with A. Werth, Land Economics, 57(2), May 1981, pp. 197-212.

"An Analysis of Department of Energy Residential Appliance Efficiency Standards," The Energy Journal, 2(3), Summer 1981, pp. 49-70.

"A Note on the Use of Aggregate Data in Individual Choice Models: Discrete Consumer Choice Among Alternative Fuels for Residential Appliances," Journal of Econometrics, 18, 1982, pp. 313-335.

"A Probability Model of Oligopoly Pricing," Applied Economics, 14(3), June 1982, pp. 219-234.

"A Note on Externalities and the Placement of Property Rights: An Alternative Formulation to the Standard Pigouvian Results," The International Review of Law and Economics, 2(1), June 1982, pp. 111-118.

"A Note on the Appropriateness of Conditional Logit for the Modeling of Residential Fuel Choice," Land Economics, 58, November 1982, pp. 478-87.

"The Estimation of Short-Run Household Electricity Demand Using Pooled Aggregate Data," Journal of Business and Economic Statistics, 1(2), April 1983, pp. 127-135.

"The Importance of Technology and Fuel Choice in the Analysis of Utility-Sponsored Conservation Strategies for Residential Water Heating," The Energy Journal, 5(3), July 1984.

"Measuring the Effects of Utility-Sponsored Conservation Programs - Do the Programs Work," Energy Systems and Policy, 8(3), 1984.

"The Estimation of the Effects of Utility-Sponsored Conservation Programs," with M. Doane, Applied Economics, 18(1), 1986, pp. 1-25.

"Household Discount Rates Revisited," with M. Doane, The Energy Journal, 7(1), Winter 1986.

"Energy Conservation Programmes: The Analysis and Measurement of Their Effects," Energy Policy, October 1986.

"Product Quality and Market Efficiency: The Effect of Product Recalls on Resale Prices and Firm Valuation," The Review of Economics and Statistics, 69(2), May 1987, pp. 367-371.

"The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," with M. Doane, The Journal of Law, Economics and Organization, Fall 1987.

"Taking the Con Out of Conservation Program Evaluation" with Michael Doane, Resources and Energy, 9, 1987, pp. 187-207.

"Self-Selection Bias in the Evaluation of Voluntary Energy Conservation Programs," Review of Economics and Statistics, 70(3), August 1988.

"Household Preference for Interruptible Rate Options and the Revealed Value of Service Reliability," with

M. Doane and C.K. Woo, The Energy Journal, 9, 1988.

"Households' Perceived Value of Service Reliability: An Analysis of Contingent Valuation Data," with M. Doane and C.K. Woo, The Energy Journal, 9, 1988.

"An Empirical Model of Product Design and Pricing Strategy," International Journal of Industrial Organization, 7(4), December 1989.

"Hedonic Methods for Evaluating Product Design and Pricing Strategies," Journal of Economics and Business, 41(3), August 1989.

"Status Quo Bias in the Measurement of Value of Service," with M. Doane and C.K. Woo, Resources and Energy, Volume 12, 1990, pp. 197-214.

"Product Emulation Strategies in the Presence of Reputation Effects and Network Externalities: Some Evidence from the Minicomputer Industry," with D. Teece, Economics of Innovation and New Technology, Volume 1, 1990, pp. 157-182.

"Consumer Rationality and the Status Quo," with M. Doane and C.K. Woo, Quarterly Journal of Economics, Volume 106, February, 1991, pp. 141-162.

"A Monte Carlo Analysis of Alternative Estimators in Models Involving Selectivity," Journal of Business and Economic Statistics, 9(1), January, 1991, pp. 41-49.

"Assessing Market Power in Regimes of Rapid Technological Change," with D. Teece, W. Mitchell and T. Jorde, Industrial and Corporate Change, 2(3), 1993, pp. 317-350.

"Estimation of Household Preferences for Long Distance Telecommunications Carrier," with Z. Naqvi, Journal of Regulatory Economics, 6(2), May, 1994, pp. 197-220.

"Strategic Rate Making in the Context of Dynamic Ramsey Pricing," with K. Jensen and K. Seiden, Applied Economics, 26, 1994, pp. 363-374.

"Incentive Regulation: Market Based Pollution Control for the Real World?" with David Wheeler, in Claudio Frischtak, ed., Regulatory Policies and Reform: A Comparative Perspective, World Bank/Oxford University Press, chapter 11, 1996.

"The Efficiency Effects of Electric Utility Mergers: Lessons from Statistical Cost Analysis," Energy Law Journal, 17(2), Fall 1996.

"The Use of Regression Techniques in Transfer Price Analysis," with Delores Wright and J.D. Opdyke, European Taxation, International Bureau of Fiscal Documentation, TP, Suppl. No. 18, July 1996.

"The Regulatory Contract and Restructuring: A Modest Proposal," with R.D. Tabors, The Electricity Journal, 9(10), December 1996.

"Predicting the Efficiency Effects of Mergers," Journal of Forensic Economics, 9(3), Fall 1996.

"The Cost of Air Pollution Abatement," with David Wheeler and Manjula Singh, Applied Economics,

Volume 29, 1997.

"Optimal Operating Arrangements in the Restructured World: Economic Issues", with R.D. Tabors, Energy Policy, 25(7), 1997.

"The Use of Statistical Methods in Disparate Impact Cases: The Northern Mariana Islands Case," Litigation Economics Digest, 3(1), Summer 1998.

"How Good a Deal Was the Tobacco Settlement?: Assessing Payments to Massachusetts", with David Cutler, Arnold Epstein, Richard Frank, Charles King, Joseph Newhouse, Elizabeth Richardson and Meredith Rosenthal, Journal of Risk and Uncertainty, 21(2/3), 2000.

"Price-Performance Competition and the Merger Guidelines," Review of Industrial Organization , 18, 2001.

"The Microeconomic Analysis of Pollution, Pollution Abatement and Pollution Abatement Regulation," with D. Wheeler, The Pacific and Asian Journal of Energy, 10(2), December 2000.

"The Economic Impacts of the Tobacco Settlement," with David Cutler, Jonathan Gruber, Mary Beth Landrum, Joseph Newhouse and Meredith Rosenthal, Journal of Policy Analysis and Management, 21(1), Winter 2002.

“Tobacco manufacturers are now compensating states for smoking-related costs. How will this affect the economy?”, with David Cutler, Jonathan Gruber, Joseph Newhouse and Meredith Rosenthal, Regional Review, Federal Reserve Bank of Boston, 12(2), 2002, Quarter 2.

"An Analysis of Price Discrimination in Brand Name Drug Wholesaling," with Richard Frank and Benjamin Sommers, International Journal of the Economics of Business, forthcoming 2007.

Contributions of economic forecasting articles to the popular press, such as Management Forum and Nations Business

PAPERS IN PROGRESS

"Welfare Measures in Discrete Choice Markets"

"Market Definition and Pharmaceutical Market Competition," with Richard Frank and Haiden Huskamp

CONFERENCE PAPERS AND PRESENTATIONS

"Policies To Maximize Economic Growth In Japan," in Foreign Experience with Monetary Policies to Promote Economic and Social Priority Programs, Committee on Banking and Currency, 92nd Congress, Washington, May, 1972.

Comments on "Econometric Models of Choice and Utilization of Energy-Using Durables" by D. Brownstone, Electric Power Research Institute Workshop on the Choice and Utilization of Energy Using

Durables, Boston, Nov. 1-2, 1979.

"Market Penetration of Energy Technologies," talk given in the Boston University 1980 Spring Lecture Series, "Man and Energy: Energy and Regional Growth," 1979.

"Discrete Consumer Choice among Alternative Fuels and New Technologies for Residential Energy-Using Appliances," MIT Energy Laboratory Working Paper, #MIT-EL-79-049WP, August, 1979. Paper given at the TIMS/ORSA Meetings, "Market Penetration Assessment of New Energy Technologies," May 4-7, 1980, and at the MIT Industrial Liaison Program, "The Future Demand for Energy," March l8, 1980.

"Department of Energy Residential Appliance Efficiency Standards-An Overview," Papers and Proceedings, Second Annual North American Meeting of the International Association of Energy Economists, October 1980.

Comments on "A Review of the Conditional Demand Approach to Electricity Demand Estimation," by S. George, Electric Power Research Institute Workshop on End-Use Modeling and Conservation Analysis, Atlanta, Nov. 17-19, 1980.

"Measuring the Effects of Utility Sponsored Conservation Programs." Paper presented at the Fourth Symposium on Electric Utility Load Forecasting: Focus on the Short Run, Electric Power Research Institute Workshop, Dallas, Texas, December 1982.

"Measuring the Impact of Utility Residential Conservation Programs: Two Case Studies," with S. Braithwait and M. Doane. Paper presented in the Electric Power Research Institute National Symposium Proceedings, Annual Review of Demand and Conservation, Atlanta, May 1984, and Buildings and Their Energy Systems, St. Louis, October 1984.

"Measuring Program-Induced Energy Savings: A Comparison of Alternating Methods," with M. Doane, in Electric Power Research Institute National Symposium Proceedings, Energy Expo 1985: Meeting Energy Challenges, Peragon Press.

"Taking the Con Out of Conservation Program Evaluation." Paper presented at "Energy Conservation Program Evaluation," Argonne National Laboratory Conference, Chicago, August, 1985, and at the Eighth Annual North American Conference of the International Association of Energy Economists, MIT, Cambridge, November 1986.

"Quality and Efficiency of Limited Information Maximum Likelihood Estimators: A Monte Carlo Simulation Study," with M. Sonnenschein. Paper presented at the 27th International Meeting of the Institute of Management Sciences, Brisbane, Australia, 1986.

"Product Emulation Strategies in the Presence of Reputation Effects and Network Externalities: Some Evidence from the Minicomputer Industry," with D. Teece. Paper presented at National Bureau of Economic Research, Conference on Productivity Measurement, July, 1987, and Stanford Center for Economic Policy Research Conference on Compatibility Standards and Information Technology: Business Strategy and Public Policy Issues, February 1989.

Comments and discussion on "Efficient Postal Discounts" by John Panzar and "Efficient Component Pricing for Postal Service: It Ain't That Efficient!" by Michael Crew and Paul Kleindorfer -- both papers presented at the Session on Postal Economics, American Economic Association Meetings, Washington

D.C., January 7, 1995.

"Making Electricity Markets Work: Competitive Models and Constraints to Competition," paper given at the Conference, "Keeping the Lights On: Technical and Institutional Issues in a Restructured Electricity Industry," Massachusetts Institute of Technology, Cambridge, October 19-20, 1995.

"A Discussion of Market Power in a Non-Merger Context: RTG/Power Pool Commercial Practice Issues," paper given at the Conference "Market Power: The Antitrust Dilemma for the Electric Industry," Washington DC, March 4, 1996.

Comments and discussion on "Electricity Data Needs: An Economic Perspective," by Douglas Hale, Office of Statistical Standards, Meeting of the American Statistical Association Committee on Energy Statistics, Washington, DC, Fall 1996.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY (MIT); ANALYSIS GROUP, INC., (AG); LAW AND ECONOMICS CONSULTING GROUP (LECG); AND ARTHUR D. LITTLE, INC., (ADL) REPORTS

MIT Related

MIT Energy Management and Economics Group, The Conditional/Generalized Maximum Likelihood Logit Computer Program: Instructions for Use, MIT Energy Laboratory Report, MIT-EL-78-013, June 1978.

MIT Model Assessment Group, Independent Assessment of Energy Policy Models: Two Case Studies, Report to the Electric Power Research Institute, EPRI-EA-1071, Project 1015-1, May 1979.

MIT Residential Energy Demand Group, Aggregate Pooled Data Utilized and/or Developed for Residential Energy Demand, MIT Energy Laboratory Working Paper, #MIT-EL-79-047, August 1979.

MIT Energy Laboratory, Assessment of the Appropriate Methods of Incorporating Appliance Engineering Analyses and Data into Residential End-Use Demand Models, Report to the Electric Power Research Institute, Number EA 4146, 1982.

Hartman, Suggested Procedures for the Validation of Bonneville Power Administration's Residential Energy Forecasting Model, Report to Bonneville Power Administration, June 1983.

R. Hartman and P. Spinney, Incentive Regulation for the Restructured Electric Power Industry in Massachusetts, MIT School of Engineering, Laboratory for Electromagnetic and Electronic Systems, LEES Working Paper wp-96-005, September, 1996.

AG Related

AG, Recent Contributions to the Theory and Measurement of Service Reliability, Task 1 Report, Prepared for Niagara Mohawk Power Corporation, September, 1987.

AG, Review of Existing Niagara Mohawk Power Corporation Procedures for Collecting Data on Outage

Costs, Task 2 Report, Prepared for the Niagara Mohawk Power Corporation, September, 1987.

AG, The Design of Methods and Implementation Procedures to Collect Data on Customer Outage Costs and the Value of Service Reliability, Task 3 Report, Prepared for the Niagara Mohawk Power Corporation, January 1988.

AG, Customer Outage Costs and the Value of Service Reliability: Draft Analysis Plan for Residential and Large Commercial/ Industrial Customers, Draft Report prepared for the Niagara Mohawk Power Corporation, August 1988.

LECG Related

LECG, Optimal Plant and Firm Size in the Electric Power Industry: Report on Academic/Industry Literature, Report to the Division of Ratepayer Advocates, California Public Utility Commission, August, 24, 1989.

LECG, Analysis of Competitive Consequences and Efficiency Claims for the Proposed Merger Between Southern California Edison and San Diego Gas and Electric, Report to the Division of Ratepayer Advocates, California Public Utility Commission, December, 1989.

LECG, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company, Report to the California Public Utilities Commission, Division of Rate Payer Advocates, Application 88-12-035, February, 1990, Exhibit 10,500;

LECG, A Critique of the Commodity Futures Trading Commission (CFTC) Study: "Economic Analysis of Dual Trading on Commodity Exchanges", Report prepared for the Coffee, Sugar and Cocoa Exchange, Inc., March, 1990

LECG, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company -Surrebuttal: Econometric Analysis of Merger Impacts, Report to the California Public Utilities Commission, Division of Rate Payer Advocates, Application 88-12-035, July, 1990, Exhibit 10,511.

LECG, A Critical Analysis of the Proposed Merger Between Kansas Power and Light Company and Kansas Gas and Electric Company, Report to the Missouri Public Service Commission, March 25, 1991.

LECG, Petitioners' Economic Testimony in the Matter of Certain Carbon Steel Flat Products, Final Hearing before the United States International Trade Commission, June 29-30, 1993.

LECG, Petitioners' Post Hearing Brief in the Matter of Certain Carbon Steel Flat Products, before the United States International Trade Commission, July 7, 1993.

Hartman, "Returns to Scale and Scope in the Electric Utility Industry: Review of Existing Econometric Analyses and Examination of Their Applicability to the Proposed Merger Between Southern California Edison and the San Diego Gas & Electric Company," LECG Working paper, September, 1989.

Hartman, "Measuring Productivity for the United States Postal Services," Report to the Resource Technology Center of Arthur D. Little, Inc. and the United States Postal Services, January, 1991.

Hartman, "The Relevance of Incentive Regulation to the United States Postal Service," Report to the Resource Technology Center of Arthur D. Little, Inc. and the United States Postal Services, February, 1992.

Hartman, "The Relevance of Incentive Regulation for Environmental Policy Modeling," Report to the World Bank, February, 1992.

Hartman, "Issues in the Valuation and Aggregation of Goods and Services: A Concept Paper," Report to the World Bank, Socio-Economic Data Division, International Economics Department, May, 1992.

Hartman, "A Framework for the Spatial Development of Infrastructure: The Electric Power Industry," Report to the Government of Indonesia, Bappenas, Jakarta, July, 1992.

Hartman, "Stimulating Pollution Abatement Efforts in the Brantas River Basin," Report to World Bank, Indonesian Environmental Mission, Jakarta, August, 1992.

Hartman, "Policies to Control Emissions from Energy Production and Use in Thailand," Report to the World Bank, East Asia Country Operations, January, 1993.

World Bank, Thailand: Managing Environmental Impacts in a High-Growth Economy, Country Economic Report, April 5, 1993.

ADL Related

ADL, Growth Patterns of U.S. Industries and Markets in 1973: The Year Ahead, 1972.

ADL, Tourism in Maryland: Analysis and Recommendations, Report to the Maryland Department of Economic and Community Development, 1972.

ADL, Economic Impact Study of the Pollution Abatement Equipment Industry, Report to the Environmental Protection Agency, December 1972.

ADL, Economic Transition of Distressed Communities, An Analytical Study, Report to the Economic Development Administration, U.S. Department of Commerce, 1974.

ADL, Tourism in Maine: Analysis and Recommendations, Report to the Maine Vacation Travel Analysis Committee, May 1974.

ADL, Tourism in San Diego: Its Economic, Fiscal and Environmental Impacts, Report to the City of San Diego, November 1974.

ADL, The Economic Impact of Proposed OSHA Airborne Arsenic Standards, Report to the American Smelting and Refining Company, June 1975.

ADL, Preliminary Projections of New England's Energy Requirements, Report to the New England Regional Commission, September 1975.

ADL, Economic Impact of Environmental Regulations on the U.S. Copper Industry, Preliminary Rough

Draft Report to the U.S. Environmental Protection Agency, 1976.

ADL, Pacific Gas and Electric Company Estimates of Energy Conservation Potential, 1980-2000, Report to the Public Utilities Commission of the State of California, June 1980.

ADL, Southern California Edison Estimates of Electricity Conservation Potential, Report to the Public Utilities Commission of the State of California, June 1981.

ADL, Southern California Edison Projections of Conservation Goals 1982-1986, Report to the California Public Utilities Commission for Southern California Edison, October 1981.

ADL, Estimate of Conservation Penetration for the Southern California Gas Company Service Area, 1981-1986, Report to the Southern California Gas Company, November 1981.

ADL, Electricity and Natural Gas Conservation Potential in the San Diego Gas and Electric Service Territory, Report to the Public Utility Commission of the State of California, April 1982.

ADL, Integrated Conservation Planning/Load Forecasting System Technical Users Guide, Report to San Diego Gas and Electric Company, Vols. I and II, Summer 1982.

ADL, A Method for Evaluating Residential Conservation Programs: Interim Report, Report to the Electric Power Research Institute, RP 1587, March 1983.

ADL, Measuring the Impact of Residential Conservation, Volume II: An Econometric Analysis of Portland General Electric Company Data, Report to the Electric Power Research Institute, EPRI EA-3606, September 1985.

ADL, Measuring the Impact of Residential Conservation, Volume III: An Econometric Analysis of General Public Utilities Inc. Data, Report to the Electric Power Research Institute, EPRI EA-3606, Project 1587, May 1986.

ADL, Measuring the Impact of Residential Conservation, Volumes IV: A Comparison of Alternative Methods, Report to the Electric Power Research Institute, EPRI EA-3606, Project 1587, May 1986.

ADL, Evaluation of EUA's Proposed Acquisitions of Unitil and Fitchburg Electric, Report to Gaston and Snow, March 12, 1990.

Hartman, "Critical Review of Selected Energy End-Use Models and Proposed Specifications for PG&E End-Use Modeling Efforts," Arthur D. Little, Inc., Working Memorandum #13 for Pacific Gas and Electric Co., June 1979, Arthur D. Little, San Francisco.

Hartman, "Potential State-of-the Art Energy Demand Models for Use in Developing an Integrated Natural Gas Forecasting and Conservation Planning System for Southern California Gas Company," Arthur D. Little Working Paper, June 1981, Arthur D. Little, San Francisco.

Hartman, "A Critical Review of the Delmarva 1981-2000 Load Forecast," with James C. O'Keefe, Arthur D. Little Working Paper, September 1981, Arthur D. Little, San Francisco.

Hartman, "Analyzing and Measuring the Effects of Utility Sponsored Conservation Programs," Arthur D.

Little Energy Group Discussion Paper, September 1982, Arthur D. Little, San Francisco.

UNPUBLISHED WORKING PAPERS

"An Examination of the Use of Probability Modeling for the Analysis of Inter-fuel Substitution in Residential Fuel Demand," with M. Hollyer, MIT Energy Lab Working Paper #MIT-EL-77-0l8WP, July 1977.

"A Critical Survey of Three Copper Industry Models and Their Policy Uses," MIT Energy Lab Working Paper #MIT-EL-77-028WP, September 1977.

"The Evolutionary Model of Technical Change: Historical Evidence from Great Britain and the United States:, with D. Wheeler, mimeo, December 1977.

"A Critical Review of Single Fuel and Interfuel Substitution Residential Energy Demand Models," MIT Energy Laboratory Report #MIT-EL-78-003, March 1978.

"A Generalized Logit Formulation of Individual Choice," MIT Energy Laboratory Working Paper #MIT-EL- 79-0l0WP, February 1979.

"A Model of Residential Energy Demand," MIT Energy Laboratory Working Paper, #MIT-EL-79-041WP, August 1979.

"The Incorporation of Solar Photovoltaics into a Model of Residential Energy Demand," MIT Energy Laboratory Working Paper #MIT-El 80-014WP, May 1980.

"Consumer Choice Among Alternative Fuels and Appliance Technologies: An Analysis of the Effects of Alternative Energy Conservation Strategies," MIT Energy Laboratory Working Paper #MIT-EL 82-036WP, June 1982.

"Estimation of Hedonic Supply Curves For Residential Water Heaters Using Technical Data and Federal Testing Guidelines," with Alan Cox and Mary Litterman, MIT Energy Laboratory Working Paper #MIT-EL 82-037WP, June 1982.

"A Monte Carlo Examination of the Heckman and the Manski-Lerman Estimators in Discrete/Continuous Models of Demand," October 1986.

"The Value of Service Reliability: Alternative Welfare Measures," with C.K. Woo, October, 1988.

"The Use of Hedonic Analysis in Defining and Measuring Market Size: The Extension of the Merger Guidelines to Heterogeneous Products," Working Paper No. 91-12, Program in Law and Economics. School of Law, Boalt Hall

EXPERIENCE IN CONSULTING AND EXPERT TESTIMONY

Overview of Qualifications

Dr. Hartman is an economist specializing in microeconomics, econometrics and the study of industrial organization. Microeconomics is the science used to analyze and characterize the behavior of groups of consumers and producers that constitute markets. Econometrics is a science that makes use of mathematics and statistics to measure and quantify economic behavior and economic phenomena in markets. The study of industrial organization makes use of both microeconomic theory and econometrics. It focuses upon the structure, conduct and performance of the participants (consumers and producing firms) in markets and industries, for the purposes of predicting behavior and addressing such policy issues as antitrust, regulation and industrial policy.

He has taught economics, conducted economic research and provided economic consulting in his areas of specialization for thirty-five years. He taught economics as an Assistant Professor and Associate Professor within the Department of Economics at Boston University over the period 1977-1988. He taught economics as a Visiting Associate Professor and member of the Visiting Faculty at the School of Law, Boalt Hall, University of California at Berkeley over the period 1988-1993. He was a member of the research faculty at MIT over the period 1977-1982, during which time he conducted research in energy markets for the United States Department of Energy. During the same time, he declined the offer of a Visiting Assistant Professorship within the Department of Applied Economics at MIT, and instead lectured on a selective basis. Since 1971, he has consulted to federal and state governmental bodies, private corporations, law firms, consulting companies, research organizations and international lending organizations. He has been and continues to be a research referee for a variety of academic journals, including the top academic journals in the country. He is the author of more than 100 refereed journal articles, book chapters and research/consulting reports.

He has submitted oral and written testimony before federal and state courts of law and regulatory commissions. His testimony as an expert witness has addressed anticompetitive behavior, merger efficiencies, breach of contract, employment discrimination, patent infringement, class certification and the estimation of damages in a variety of markets and industries including, but not limited to, the pharmaceutical industry, the health care services industry, the electric power industry, the banking industry, the agrochemical industry, the copper industry, the defense industry, the cable TV industry, the tobacco industry, the electrical and mechanical carbon products industry, the medical devices industry and the construction industry. He has consulted to counsel on litigation matters in a broader array of markets.

While his experience has been broadly-based across industries, two industries/markets have been primary subjects of substantial consulting, research and litigation support.

Experience in Energy Markets and Regulated Industries

Since 1977, Dr. Hartman's expertise and experience have involved regulated industries generally and the markets for electric power and natural gas specifically. His consulting and/or litigation assignments have included load forecasting, evaluation of conservation and load management programs, econometric cost analysis, analysis of revenue requirements and rate-making, analysis of value of service reliability, the analysis of mergers and acquisitions, analysis of industry restructuring, analysis of manipulation of spot and future prices in energy markets, and analysis of contract damages arising from DOE's partial breach of the Standard Contract regarding storage of nuclear waste. In these assignments, Dr. Hartman has consulted for such clients as Arizona Public Service, the Pacific Gas and Electric Company, the Southern California

Edison Company, the Southern California Gas Company, the San Diego Gas and Electric Company, Portland General Electric Company, Bonneville Power Administration, General Public Utilities, Northeast Utilities, Niagara Mohawk Power Corporation, the Delmarva Power Corporation, Florida Power Corporation, Sithe Energies, the California Energy Commission and Public Utilities Commission, the Missouri Public Service Commission, the Rhode Island Division of Public Utilities, the Attorney General of the State of Massachusetts, the Electric Power Research Institute, the Gas Research Institute, the U.S. Department of Energy, the U.S. Department of Justice, the World Bank, and the governments of Indonesia and Thailand. He has consulted for a number of other clients whose identity must remain confidential.

Experience in Health Care and Pharmaceutical Markets

Over the past 10 years, Dr. Hartman has participated as testifying or consulting expert in a wide array of matters related to health-care markets generally and, more specifically, markets for medical devices and pharmaceutical products. For examples, working with a team of health care experts, he submitted written testimony assessing and measuring the impacts of smoking on Medicaid health care costs in the Commonwealth of Massachusetts. He submitted testimony analyzing the competitive impacts upon and damages to a class of dental laboratories caused by the restrictive dealer practices of a dominant U.S. manufacturer of medical prostheses - false teeth. He consulted to the group of wholesaler defendants in the Brand-Name Prescription Drugs Antitrust Litigation, addressing issues of wholesaler pricing across classes of trade. He consulted to counsel to a manufacturer of cardiovascular stents and other related devices in a variety of patent infringement matters, addressing such issues as competition, market penetration of new products and economic damages arising from patent infringement. He consulted for one group of private plaintiffs in the antitrust matter regarding the prescription drugs lorazepam & clorazepate and for the Federal Trade Commission in the matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P. and Andrx Corporation concerning antitrust claims involving the prescription drug Cardizem CD. That consultation addressed issues of market definition, product competition, class certification and damage estimation. He consulted to counsel on the matter of damages to the class of direct purchasers of the prescription drug Taxol and on the matter of damages to the class of indirect end-payer purchasers of the prescription drugs K-Dur, Augmentin, Bextra, Celebrex and Vioxx. He submitted testimony addressing class certification, liability and/or damages for the class of end-payer purchasers in antitrust or RICO litigation concerning the prescription drugs Hytrin, BuSpar, Relafen, Lupron, Premarin, Cipro in the states of New York and California and in the United States, and Neurontin in the United States and Pennsylvania. In the MDL AWP litigation, he submitted testimony in support of the certification of the class of end-payer purchasers of those pharmaceutical products produced by AstraZeneca, the Bristol-Myers Squibb Group, the Johnson & Johnson Group, the GlaxoSmithKline Group and the Schering Plough Group that were alleged to have been the subject of a scheme to fraudulently inflate their Average Wholesale Price (AWP); he subsequently submitted testimony supporting findings of causation, liability and the calculation of damages for those end-payer groups for which class certification was granted. He has consulted to and/or submitted testimony for the Offices of the Attorneys General for the states of New York, Connecticut, Montana and Nevada in analogous matters. His testimony has been the basis for the certification of class in a variety of these matters. His testimony has been the basis for approval supporting settlement agreements in a variety of these and other pharmaceutical matters.

Specific Assignments

1972-1975: In consultation with Arthur D. Little, Inc., Dr. Hartman developed economic impact models to assess the effects of environmental regulations upon the U.S. pollution abatement equipment industry and upon a particular U.S. copper smelting company.

1972-1975: In consultation with Arthur D. Little, Inc., Dr. Hartman developed economic models to

assess the regional macroeconomic and industrial impacts of alternative strategies to promote tourism-related industries. The models were used in the United States by the states of Maryland and Maine and for the Philadelphia Bicentennial Commission. Internationally, the models were used by the Ministry of Planning of Mexico to assess the national and regional importance of tourism coming into Acapulco.

1976-1977: Consultation with Arthur D. Little, Inc. for the U.S. Environmental Protection Agency. The effort involved the design, estimation and implementation of an econometric simulation model that was used to assess the impact of pollution abatement legislation on the U.S. copper industry. The model was designed to incorporate engineering cost estimates attributable to the abatement legislation while accounting for the noncompetitive pricing behavior in the industry. The model was used to evaluate and revise proposed abatement legislation. This analysis was the basis for Dr. Hartman's Ph.D. dissertation and several of his publications.

1977-1982: Working as the testifying expert, Dr. Hartman analyzed the presence of a price-fixing conspiracy among the major U.S. copper producers during the 1970's. His testimony addressed issues of liability and developed a model of damages. See

> Affidavit to United States District Court for the Southern District of New York, *J.N. Futia Co., Inc., Plaintiff, Against Phelps Dodge Corporation, et al., Defendants,* 78 Civ. 4547 (ADS), 1978.
>
> Deposition for United States District Court, Southern District of New York for *Reading Industries, Inc., et al. (Plaintiffs) against Kennecott Copper Corporation, et al. (Defendants)*, 17 Civ. 1736 (MEL), 1982.

1979: Working for the California Energy Commission, Dr. Hartman developed and presented a Statement of Opinion and Critical Review of Selected Energy End-Use Models and Proposed Specifications for PG&E End-Use Modeling Efforts before the California Energy Commission Hearings on Utility Construction and Siting, November 26-30, 1979.

1984: Testifying expert for the class of all individuals who employed the services of members of Massachusetts Furniture and Piano Movers Association. The analysis developed an econometric model to assist in certifying the class and measuring the damages common to that class. See

> Affidavit to United States District Court for the District of Massachusetts in the Matter of *Kenett Corporation et al v. Massachusetts Furniture and Piano Movers Association Inc. et al*, May 1984, Civil Action No. 82-140-Z.

1984-1986: In consultation with the U. S. Postal Service, Dr. Hartman identified appropriate econometric methods for analysis of the determinants of Postal Service costs. The particular methods he suggested were "hedonic" cost techniques, which are specifically designed to account for the fact that both increased levels of production and improved product attributes increase costs. The techniques assisted the Postal Service in quantification of the cost impacts of the attributes of service quality for alternative classes of service. For example, the techniques allowed for estimation of the differential cost impacts of alternative service priorities, size and weight attributes of the various classes of mail.

He later applied these techniques for a group of second class mailers. The analysis was introduced before the Postal Service Commission to assess whether proposed postal rate changes reflected actual costs.

1984-1986: The development of econometrically-based strategic planning models, which allow for

estimation of the effects on corporate profits of alternative product design and pricing strategies. The models allow for examining specific design strategies by explicitly incorporating detailed product attributes. The models were developed for Westin Hotels and Shell Oil. The Westin models have been implemented into an interactive PC tool that facilitates pricing decisions at the front desk.

1985: For analysis presented before the International Trade Commission, Dr. Hartman helped develop and estimate a model to evaluate the domestic effects of importation of certain synthetic aramid fibers. The analysis was used in adjudicating an international patent infringement complaint.

1985-1986: Dr. Hartman participated in an analysis of one of the nation's largest mutual funds. The study was undertaken as part of a class action alleging inappropriate management fees. The study assessed competition in the money market mutual fund industry. It measured investors' sensitivity to changes in yield and to the level of services provided. It also statistically identified the determinants of the costs of providing mutual fund services.

1985-1986: The development for GTE Laboratories of econometric demand models for analysis and measurement of the determinants of demand for telecommunications services. The models explicitly address the separate customer decisions to subscribe to one of several telecommunications carriers and the demand for telecommunications services, conditional upon the subscription decision. The analysis was employed by GTE to assist their subsidiary, GTE Sprint, in the design of marketable services, where the services were differentiated by tariff, perceived service quality, provider reputation, and specialized customer services. The analysis is summarized in the paper

> "Estimation of Household Preferences for Long Distance Telecommunications Carrier", *Journal of Regulatory Economics*, Volume 6, 1994.

1985-Present: Dr. Hartman has performed a variety of economic damage analyses in cases of personal injury, wrongful injury and wrongful death. He has worked for both plaintiff and defendant. He has been deposed in such matters as recently as 1995.

1986: For a major natural gas pipeline, preparation of an analysis of the effects of natural gas deregulation as proposed in the Federal Energy Regulatory Commission's Notice of Proposed Rulemaking No. 436.

1986-1987: Working for the class of owners of selected General Motors' X Cars and VW Rabbits, Dr. Hartman specified and estimated econometric models that assisted in the certification of class and estimation of class damages. The damages flowed directly from allegedly-concealed design flaws in these automobiles. The methods are described in

> "The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," with M. Doane, *The Journal of Law, Economics and Organization*, Fall 1987.

1986-1987: Development of damage models for litigation in high technology industries. The models were developed in several cases. One involved alleged patent infringement by a major Japanese semiconductor firm, and the second involved market foreclosure of a domestic minicomputer emulator. In these efforts, Dr. Hartman developed econometric models to estimate the market potential, absent the violation, for the particular product foreclosed or whose patent was infringed. The methods are described generically in

"Product Emulation Strategies in the Presence of Reputation Effects and Network Externalities: Some Evidence from the Minicomputer Industry," with D. Teece, *Economics of Innovation and New Technology*, Volume 1, 1990.

1987: Analysis of the competitive effects of relaxing the restrictions on the Bell Regional Operating Companies regarding their vertical extension upstream into equipment manufacture and downstream into the provision of selected telecommunication services. The study was introduced before Judge Greene in the triennial review of the divestiture of the Bell operating companies from AT&T.

1987-1988: For a major gas utility, participation in analysis of the economic effects arising if bypass of an existing pipeline were allowed by state and federal regulation. The analysis developed methods for assessing when competitive bypass is socially desirable. The analysis also developed and used an econometric model to simulate the effects of bypass on demand and prices.

1988: Analysis of the competitive effects the acquisition of trade secrets through the predatory hiring of a competitor's essential labor force. See

Analysis submitted in testimony in the case *Universal Analytics Inc. v. MacNeil Schwendler, Corp*.

1988-1989: As part of their proposed acquisition of Public Service of New Hampshire, Dr. Hartman was retained by Northeast Utilities, Inc. to develop and estimate load forecasting models. The models were used to assess the demand implications of alternative rate assumptions proposed as part of the acquisition. The forecasts were introduced as part of Northeast Utilities' filings before the bankruptcy court, the state public utility commissions, the SEC and the FERC.

1989: As part of major antitrust litigation against the leading vendors of airline computer reservation systems, Dr. Hartman helped develop liability analysis and models for the estimation of damages.

1989: As a proposed testifying expert for Parnelli Jones, Inc., Dr. Hartman analyzed the antitrust implications of Firestone's retail trade practices, particularly alleged vertical and horizontal restraints of trade. He designed damage models for the alleged violations.

1989 - Present: Dr. Hartman has performed and continues to perform the market analyses required for Hart-Scott-Rodino applications and second requests supporting mergers and acquisitions in a variety of industries, including specialty chemicals, airlines, health care and medical diagnostic products, and energy products and services.

1989-1990: Dr. Hartman participated as a principal investigator and testifying expert for the Division of RatePayer Advocates of the California Public Utility Commission in an analysis of the economic and legal implications of the proposed merger between Southern California Edison Company and San Diego Gas and Electric Company. Dr. Hartman's responsibilities included overall study design, econometric analysis of scale and scope economies arising with the merger, and analysis of efficiencies purportedly arising with the coordination of the demand-side management programs of the two utilities. His direct and surrebuttal testimony is found in

California Public Utilities Commission, Division of Rate Payer Advocates, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company, Volume V, Chapter II, Application 88-12-035, February, 1990, Exhibit 10,500; and

California Public Utilities Commission, Division of Rate Payer Advocates, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company, Surrebuttal: Econometric Analysis of Merger Impacts, Application 88-12-035, July, 1990, Exhibit 10,511.

1989-1990: Working with Arthur D. Little, Inc., Dr. Hartman participated as a principal investigator and testifying expert in a merger study for several small New England utilities within Nepool. Dr. Hartman designed and implemented a statistical study of returns to scale and scope in the industry. Using the statistical results, Dr. Hartman developed opinions regarding the efficiency effects of the proposed merger. His analysis appears as an independent Appendix to

Arthur D. Little, Inc., Evaluation of EUA's Proposed Acquisitions of UNITIL and Fitchburg, Report to Gaston and Snow, March 12, 1990, presented in support of the acquisition to the Securities and Exchange Commission and the New Hampshire Public Utilities Commission.

1990: Working for a group of commodity futures exchanges, Dr. Hartman participated as Principal Investigator in a critical review of a statistical and econometric study performed by the Commodity Futures Trading Commission. The CFTC study was developed to assess the effects of dual trading on commodity futures markets, in order to implement proposed regulations curtailing such trading.

1990: Working with Barakat and Chamberlin, Inc., Dr. Hartman developed a Ramsey pricing model for Arizona Public Service Corporation. The Ramsey pricing model was used to develop and explore alternative rate strategies for a variety of residential, commercial and industrial market segments. The analysis was submitted in formal rate hearings.

1990-1992: Working with the Technology Research Center of Arthur D. Little, Inc. for the United States Postal Service, Dr. Hartman specified and estimated econometric models to analyze the determinants of productivity for the largest 120 post offices in the United States. The econometric models are being used to identify the most and least productive offices, with the purpose of learning from the performance of the most productive offices in order to improve the performance of the least productive offices. The models are being used to design and implement incentive regulation mechanisms to increase productivity across post offices.

A second set of econometric models have been specified and estimated to quantify the effects of the attributes of alternative postal services and rate classes upon total postal service costs. The results of this analysis are being used to design postal rates for alternative classes of service which reflect the real costs of providing the services. The analysis and its results will be introduced into the postal rate hearings.

1990-1997: Working with the World Bank, Dr. Hartman has specified and is estimating a set of econometric models to measure both the level and types of pollutants emitted by United States plants and establishments and the costs of abating those pollutants. The models identify and quantify, at the plant level, the relationship between the emission of approximately 300 pollutants and the scale of production, the types of technology used, the age and characteristics of the plant and equipment used, the extent to which abatement equipment has been installed, and the costs (capital and operating) of abating alternative pollutants.

The models will be used in the following ways in developing countries and Eastern European countries: to assist the countries to predict and assess the environmental implications of reliance upon certain technologies and industries in development; to assess the effectiveness of alternative regulatory methods for

abating pollution, including effluent standards, effluent taxes, effluent licenses, technology standards, effluent banks, and alternative property right schemes; to implement incentive regulation mechanisms to better stimulate abatement compliance; and to identify and prioritize those industries that can abate certain pollutants at least cost.

As part of this effort, Dr. Hartman has also designed a specific incentive regulation system for pollution abatement compliance in Indonesia. The system is based upon the most recent theory in regulated incentive mechanisms. The system will ultimately evolve into an effluent bank or a system of effluent fees. If the effort is successful, it will form the basis for environmental institutions in other developing countries. In the process of designing this system, he has reviewed the institutional and statutory basis for environmental policy in Indonesia.

Also as part of this work, Dr. Hartman is in the process of designing the institutional and statutory structures for Environmental Protection Agencies in a variety of developing countries. The institutional structures will be designed to articulate and implement pollution abatement policies that are informed by the econometric modeling described above.

1991: Dr. Hartman participated as a principal investigator and testifying expert for the Missouri Public Service Commission in a critical analysis of the proposed merger between Kansas Power and Light Company and Kansas Gas and Electric Company. Dr. Hartman's responsibilities included overall study design, analysis of scale and scope economies arising with the merger, analysis of unanticipated transitional cost arising with the merger and an econometric event study of the stock market's response to the merger. His testimony appears in

> A Critical Analysis of the Proposed Merger Between Kansas Power and Light Company and Kansas and Electric Company, Report to the Missouri Public Service Commission, March 25, 1991.

1991: Working for the Resolution Trust Corporation in its litigation against Michael Milken and Drexel Burnham Lambert Inc., Dr. Hartman developed data and econometric models to measure the size of the relevant antitrust markets dominated by Drexel and to estimate the size of the economic damages produced by Drexel's alleged monopolization of those markets.

1991-1992: Working for the Indonesian government and the United States Agency for International Development, Dr. Hartman critically reviewed the structure of the Indonesian electric power industry and the institutions regulating that industry. The purpose of the analysis was to assist the government with privatizing their energy industries. His analysis focused upon the following: developing better data and models for predicting demand and supply; identifying and implementing more efficient industrial structures; and developing better regulatory regimes.

1992: Working for the World Bank, Dr. Hartman designed methods to measure and compare the social value of the environmental effects of alternative development projects, at the microeconomic and macroeconomic levels. His analysis focused upon standard and contingent valuation survey approaches and their use in econometric settings.

1992-1993: Working for the World Bank in Bangkok, Dr. Hartman characterized and critically analyzed the environmental effects of Thailand's energy use patterns. He focused upon the use and production of electric power, petroleum, coal and natural gas. He developed recommendations for environmental policy changes that included, but were not limited to, fuel taxes, effluent standards, technology standards, and privatization of environmental monitoring within a "bubble" policy approach.

1992-1993: Working for a biomedical company (a producer of vascular grafts) in an antitrust situation, Dr. Hartman designed and implemented survey techniques and econometric models to measure the size of the relevant markets and market power within those markets.

1992-1993: In a proceeding before the International Trade Commission, Dr. Hartman critiqued ITC econometric methods used for estimating elasticities of demand, supply and substitution among domestic and imported products. His focus was selected steel products. He formulated and estimated alternative models and methods to improve the existing estimates. He developed presentation materials for the Commission and testified before the Commission. His testimony is included in

> LECG, Petitioners' Economic Testimony in the Matter of Certain Carbon Steel Flat Products, Final Hearing before the United States International Trade Commission, June 29-30, 1993; and
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> LECG, Petitioners' Post Hearing Brief in the Matter of Certain Carbon Steel Flat Products, before the United States International Trade Commission, July 7, 1993.

1992-1997: Working for the World Bank, Dr. Hartman has designed and is currently implementing a set of regional econometric/engineering models that accurately portray and predict the economic, environmental, infrastructural and socio-demographic effects of large-scale, World-Bank-funded infrastructural projects. The models combine input-output and econometric methods.

Given the Bank experience that many of their financially-sponsored projects create significant unanticipated environmental effects, the models are designed to be broad and comprehensive enough to incorporate and predict all important effects. The models systematically characterize the relationship between resource-based economic growth and the regional environment in which that growth occurs.

The models are currently being implemented for assessing project developments in the Carajas region of the Brazilian Amazonian rain forest, which is a large, dynamic and ecologically sensitive frontier area. The methods implemented for Brazil will be generalized for analysis of economic growth in ecologically similar areas, such as the Lake Baikal region of the former Soviet Union.

1993-1994: Working for the Commonwealth of the Northern Mariana Islands, Dr. Hartman developed and presented testimony rebutting a complaint by the United States Department of Justice that the Public School System of the Commonwealth practiced employment discrimination against teachers of Filipino and native Carolinian origin. Dr. Hartman's testimony examined both hiring and compensation practices. His testimony included hedonic regression analysis of the market for public school teachers in the islands. This analysis measured how teacher attributes and qualifications determined teacher salaries and hiring. The results of the analysis indicated that salary differentials resulted from differences in teacher qualifications rather than discrimination.

1993-Present: Working either as the testifying expert or supporting other testifying experts, Dr. Hartman has participated in a variety of patent infringement cases. He has developed, supported and estimated alternative theories and measures of damages for manufacturers of coaxial cable and a variety of alternative medical devices.

1993-1998: Working as the testifying expert, Dr. Hartman developed models estimating the damages to the business of a construction general contractor that were caused by the malicious prosecution of the contractor's insurance company.

1994: Working for the United States Wheat Associates in a proceeding before the ITC, Dr. Hartman designed and implemented an econometric study to assess and quantify the extent to which Canadian Wheat Board imports into the U.S. undersold domestic supplies and thereby materially interfered with the United States Department of Agriculture Wheat Program. The econometric study was hedonic. The study measured how non-price attributes are valued in U.S. wheat markets. The non-price attributes analyzed included such things as protein content, shipment defects, moisture content and a number of end-use performance characteristics. Having measured the value of these attributes in U.S. markets, the analysis indicated how the Canadian Wheat Board fixed import prices below market levels, given the attributes of the imported wheat.

1994: Working as a testifying expert for Gallo Wines in a proceeding before the ITC, Dr. Hartman designed and implemented a statistical study of the US wine industry that analyzed the impacts of Chilean wine imports upon the domestic industry that would result from the inclusion of Chile in a Free Trade Agreement with the US.

1994: Working as a testifying expert for an insurer of a member of the Asbestos Claims Facility and Center for Claims Resolution, Dr. Hartman developed a statistical analysis estimating alternative indemnification liabilities expected under the Settlement Share Analysis of the Center for Claims Resolution and under the tort system. The results were used to make strategic decisions regarding the desirability of participating in the Class Action Settlement relative to litigating the claims.

1994: Working for several regional Bell Operating companies, Dr. Hartman has developed models and survey procedures to analyze and quantify the determinants of demand for local services, long-distance services and PCS services. The models quantify how consumers respond to and select among alternative carriers who differentiate their services by performance attributes and vendor reputation. The models also estimate the level of service demand, conditional upon the selection of service vendor. The models are being used to quantify the nature of competition among local carriers and long-distance carriers in the Intralata market. The models are also being used to help develop bidding strategies for specific RBOCs as they participate in the FCC auctions for the PCS spectra.

1995: Working as a testifying expert for a group of independent television stations and program producers, Dr. Hartman developed an econometric analysis of the impacts of the Prime Time Access Rule (PTAR) upon the economic performance of independent television stations. The analysis was submitted to the Federal Communications Commissions as part of their consideration of the repeal of the Rule. Dr. Hartman's analysis proved that PTAR had a strong, statistically significant effect upon the economic performance of these stations, and that its repeal would adversely impact them.

His testimony is included in

The Economic Effects of Repealing the Prime Time Access Rule: Impact on Broadcasting Markets and the Syndicated Program Market, Report prepared by LECG and presented before the Federal Communications Commission, MM Docket No. 94-123, March 7, 1995.

1995: Working for a big six accounting firm, Dr. Hartman designed and implemented a hedonic regression analysis to calculate transfer prices under the comparable uncontrolled price (CUP) method. The analysis is discussed in

"The Use of Regression Techniques in Transfer Price Analysis," with Delores Wright and J.D. Opdyke, *European Taxation*, 1996.

1995-1996: Working as the testifying expert for a major high tech firm in New England, Dr. Hartman has developed rebuttal and affirmative testimony to rebut claims of age discrimination in the termination of a group of employees over forty. His rebuttal testimony involved critically reviewing statistical analyses purporting to demonstrate disparate treatment and disparate impact. His affirmative testimony has involved designing and implementing econometric models to identify and estimate those factors actually determining the compensation and termination decisions of the defendant.

1995-1996: Working as the testifying expert for the Office of Attorney General of the State of Massachusetts, Dr. Hartman has analyzed and helped develop the State's positions on the following issues: restructuring the electric utility industry in Massachusetts and New England; regulating those entities in the restructured industry that will remain subject to regulation; and valuing those assets that may be stranded as a result of restructuring. As part of the effort, Dr. Hartman also critically reviewed the restructuring proposals of the largest utilities in the state. His testimony appears in

> "The Market for Power in New England: The Competitive Implications of Restructuring," a report prepared for the Office of the Attorney General, Commonwealth of Massachusetts and submitted February 16, 1996 in support of their filing to the Department of Public Utilities as part of DPU 95-30, which was initiated August 15, 1995.

1995-1996: Working as the testifying expert, Dr. Hartman represented Florida Power Corporation in a contract dispute with Independent Power Producers. His analysis and testimony focused upon issues of damages incurred as a result of a breach of contract.

1995-1999: Working with a team of economists, Dr. Hartman represented the group of wholesalers in the retail prescription drug price fixing conspiracy case. His efforts included industry analysis and participation in cross examination of plaintiffs' experts.

1996: Working as the testifying expert for the Division of Public Utilities of the State of Rhode Island, Dr. Hartman has analyzed and helped develop the State's positions on restructuring the electric utility industry in Rhode Island and New England, for both the State's Public Utilities Commission and the FERC. As part of the effort, Dr. Hartman also critically reviewed the restructuring proposals of some of the utilities in the state. His testimony appears in

> "The Division Plan to Restructure the Electric Utility Industry in Rhode Island," Volume 2 of Supporting Testimony to the State of Rhode Island and Providence Plantations Public Utilities Commission, in re: Electric Industry Restructuring, Docket 2320, April 12, 1996.

1996: Working with a team of engineering firms, an international investment banking firm, a big six accounting firm and several national law firms, Dr. Hartman developed models of demand, supply and futures markets in restructured electric power markets to assist a major industry participant in evaluating specific alternative acquisition strategies.

1996: Working with a team of economists developing evidence for presentation before the High Court of New Zealand, Dr. Hartman critically reviewed and rebutted a variety of econometric analyses of natural gas markets and more broadly-defined energy markets in New Zealand. These analyses were used to determine the size of antitrust markets for a variety of energy products.

1996: Dr. Hartman was retained by a major mid-west utility to critically review and rebut analyses

and evidence presented before the FERC and the relevant State Commissions concerning the competitive impacts of the proposed Primergy merger.

1996-2003: Working as the testifying expert, Dr. Hartman analyzed the employment practices and procedures of the Florida Power Corporation during a reduction in force, to assess the validity of a complaint that those practices and procedures resulted in a pattern of age discrimination. In his testimony, Dr. Hartman implemented a variety of statistical and econometric analyses to address and quantify claims of disparate impact and disparate treatment.

1996-1997: Working for US Airways with a team of economists, Dr. Hartman specified and estimated a variety of econometric consumer choice models to measure customer preferences for the services of alternative air carriers in a cross section of US-European origin-destination markets. The models were used to evaluate the economic impacts of both the proposed alliance between American Airlines and British Airways and alternative proposals to condition that alliance.

1996-1997: Working as the testifying expert, Dr. Hartman represented a major national retail pharmaceuticals wholesaler in litigation brought by a regional distributor alleging monopolization of wholesale services to distinct classes of trade. His analysis addressed market definition, the analysis of competition generally and analysis of the competitive impact of specific contractual arrangements.

1997: Working with a team of experts, Dr. Hartman analyzed economic impacts of the construction of the Warrior Run Cogeneration plant which was under construction in Western Maryland and was contracted to sell power to Allegheny Power System's (APS) Maryland subsidiary, Potomac Edison.

1997: Working as the testifying expert for the Office of Ratepayer Advocates of the California Public Utilities Commission, Dr. Hartman critically reviewed the efficiencies estimated by Applicants to be induced by the proposed merger of Pacific Enterprises and Enova Corporation.

1997: Working with a team of economists, Dr. Hartman prepared affirmative and rebuttal testimony in a breach of contract matter in the pharmaceutical industry arbitrated before the International Chamber of Commerce.

1997-2000: Working as the testifying expert, Dr. Hartman developed analysis supporting certification of class and estimation of damages for the class of purchasers of thermal fax paper in the US over the period 1990-1992 who were damaged as a result of a price fixing conspiracy by major suppliers.

1998: Working as the testifying expert, Dr. Hartman analyzed the employment practices, procedures and personnel data of the Florida Power Corporation, in general and in particular, to assess the validity of a complaint that a specific employee had been subjected to racial discrimination.

1998-1999: Working with a team of economists for the Office of the Attorney General of the State of Massachusetts, Dr. Hartman developed and implemented econometric models to analyze and measure the health care costs arising under the Medicaid program that have been attributable to smoking. The analysis appears in the following documents:

> David M. Cutler, Arnold M. Epstein, Richard G. Frank, Raymond S. Hartman, Charles King and Joseph P, Newhouse, *The Impact of Smoking on Medicaid Spending in Massachusetts: 1970-1998 -- Report on Methods*, June 15, 1998;
>
> David M. Cutler, *et. al.*, *The Impact of Smoking on Medicaid Spending in Massachusetts: 1970-1998* -

- *Results From The Inclusive Approach for Adults*, July 1, 1998;

David M. Cutler, *et. al.*, *The Impact of Smoking on Medicaid Spending in Massachusetts: 1991-1998 - - Results From The Disease-Specific Approach for Adults and Overall Summary*, July 11, 1998.

Drawing upon these efforts, Dr. Hartman worked with the same team of experts to analyze the economic impacts of the Master Settlement Agreement and to present their findings to the Tobacco Fee Arbitration Panel.

1999: Working as one of two testifying experts for the Office of the Attorney General of the Commonwealth of Massachusetts, Dr. Hartman critically analyzed potential rate increases relevant to Joint Petitions introduced by both Eastern Enterprises/Colonial Gas Company and Boston Edison/Commonwealth Energy Systems. His testimony appears as

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of the Massachusetts Attorney General, in the matter of the Joint Petition of Eastern Enterprises and Colonial Gas Company For Approvals of Merger Pursuant to G.L. c. 164, §§ 96 and 94, DTE 98-128, March 26, 1999.

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of the Massachusetts Attorney General, in the matter of the Joint Petition of Boston Edison Company, Cambridge Electric Light Company, Commonwealth Electric Company and Commonwealth Gas Company For Approval of Rate Plan Pursuant to G.L. c. 164, §§ 76 and 94, DTE 99-19, April 30, 1999.

1999-2000: Dr. Hartman was retained by a group of industrial purchasers of copper to develop and implement methods and models to assess liability and measure damages in the matter involving the manipulation of the spot and future prices of copper on the London Metals Exchange by Sumitomo Corporation and Yasuo Hamanaka over the period 1987-1996.

1999-Present: Dr. Hartman consulted with counsel and the testifying expert in the development of data and models needed to certify class and measure damages in a price fixing case involving the manufacturer (Mylan) of generic clorazepate and lorazepam.

1999-2001: Working as the testifying expert, Dr. Hartman analyzed liability arising from a variety of restrictive dealer arrangements implemented by Dentsply International Inc., a U.S. manufacturer of artificial teeth, to foreclose entry by rival manufacturers from the US dental-laboratory dealer network. Dr. Hartman developed and implemented methods to measure damages to the class of dental laboratories that purchased artificial teeth from Dentsply at prices above the competitive prices that would have obtained absent the restrictive dealer arrangements.

1999-2000: Working with a team of economists for the Federal Trade Commission, Dr. Hartman analyzed the pro-competitive and anti-competitive nature of settlement agreements between generic and pioneer drug manufacturers resolving patent infringement litigation arising from certification under Paragraph IV of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act). Particular settlements analyzed include the settlement between Abbott Laboratories and Geneva Pharmaceuticals regarding the drug Hytrin and the settlement between Hoechst Marion Roussel (Aventis) and Andrx Corporation regarding the drug Cardizem.

1999-2000: Working as the testifying expert for the class of purchasers of Nine West shoes, Dr. Hartman was asked to analyze liability and measure damages arising from an alleged conspiracy to raise and maintain the prices of women's shoes manufactured by the Nine West Group Inc. and sold by a variety of general

merchandise retailers through their upscale retail department stores. The defendants in the case included Nine West Group Inc., Federated Department Stores, Inc., Dayton Hudson Corporation, Lord and Taylor, Nordstrom, Inc., May Department Stores, Macy's, Bloomingdale's, Inc., and other general merchandise retailers.

2000: Working with the testifying expert, Dr. Hartman assisted in the analysis and estimation of economic damages to a Class defined as all smokers with 20-pack years each of whom contracted lung cancer which was substantially contributed to by cigarette smoking.

2000: Working with a team of economists, Dr. Hartman developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of structural steel beams during the period 1998-1999. The work was presented before the International Trade Commission.

2001: Working with a team of economists, Dr. Hartman developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of structural steel beams and during 2000. He also developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of cold rolled and hot rolled steel during the Period of Inquiry of 1997-1999. Both efforts were presented before the International Trade Commission.

2001-present : Working as the testifying expert, Dr. Hartman developed and submitted testimony in support of class certification of and the calculation of damages to the class of indirect purchasers of the anti-hypertensive drug, Hytrin, produced by Abbott Laboratories and the generic equivalent of Hytrin, generic terazosin hydrochloride, produced by Geneva Pharmaceuticals. The class alleges monopolization and violation of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act).

2001-Present: Working as consultant and testifying expert, Dr. Hartman has been retained by counsel to the classes of indirect or direct purchasers of a variety of branded pharmaceuticals (including but not limited to Augmentin, Bextra, Cipro (New York, California, U.S.), BuSpar, Celebrex, Vioxx, K-Dur, Taxol, Lupron, Relafen, Paxil, Neurontin, Remeron, Tamoxifen, Premarin, Wellbutrin and Zyprexa) to analyze and submit testimony dealing with class certification, liability, market definition, damage calculations and settlement allocations arising from violations of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act), related state-specific unfair competition statutes and the RICO Act.

Dr. Hartman's testimony in this area has been relied upon (and cited thereto) for certification of end-payer consumer classes in the following matters:

- *In re: Terazosin Hydrochloride Antitrust Litigation*, United States District Court, Southern District of Florida, Case No. 99-MDL-1317-Seitz/Klein [Order Granting Indirect Purchaser Plaintiffs' Motions for Class Certification of State-Wide Classes, April 8, 2004]
- *In re Cipro Cases I and II*, D043543 (JCCP Nos. 4154, 4220), Court of Appeal, Fourth Appellate District, Division One, State of California [Decision affirming class certification not titled but marked as "Not to Be Published in Official Reports," Filed 7/21/04]
- *In re: Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-12239-WGY [Memorandum granting certification

for an exemplar class, May 12, 2004]

Dr. Hartman's testimony has been relied upon (and cited as necessary) for approval of proposed settlement allocations in the following matters:

- *In re: Lupron® Marketing and Sales Practices Litigation*, United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS [Memorandum and Order Approving Settlement and Certifying the Class, May 12, 2005]
- *HIP Health Plan of Florida, Inc., On Behalf of Itself and All Others Similarly Situated v. Bristol-Myers Squibb Co. and American Bioscience*, Case Number 1:01CV01295, United States District Court for the District of Columbia
- *In re Buspirone Antitrust Litigation*, MDL No. 1413, United States District Court for the Southern District of New York
- *In re Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY
- *In re Remeron Antitrust Litigation*, United States District Court, District of New Jersey, Master Docket No. 02-CV-2007

2001: Working as consultant to counsel for various U.S. steel producers, Dr. Hartman worked with a team of economists to develop econometric models to analyze and measure the impacts of imports, demand and factor price changes upon the prices of domestically produced carbon steel flat products and carbon steel long products in the Section 201 hearings before the International Trade Commission. Dr. Hartman testified before the ITC in the hearings. The Commission decided in favor of most of the products subject to these analyses.

2001: Working as consultant to counsel for Nucor Steel Corporation, Dr. Hartman worked with a team of economists to develop econometric models to analyze and measure the impacts of imports, demand and factor price changes upon the prices of domestically produced carbon steel cold rolled products for preliminary hearings before the International Trade Commission.

2001-2002: Consulting to counsel for the Plaintiff Class, Dr. Hartman analyzed the targeting of youth by cigarette advertisements in the matter *in re Devin Daniels, et. al., v. Philip Morris Companies, Inc., et. al.*, Case Number 719446, coordinated with JCCP 4042.

2001-2003: Working as testifying expert, Dr. Hartman developed and presented statistical evidence analyzing the relative performance of a particular cardiovascular surgeon litigating the fact that his surgical privileges had been revoked as a result of incompetent surgical performance and results. He testified before an arbitration panel in the matter.

2003: Working as the testifying expert for Defendants, Dr. Hartman submitted testimony analyzing the allegation of racial discrimination on the part of Wells Fargo Home Mortgage, Inc. and Norwest Mortgage, Inc.

2003: Working as a consulting expert to counsel for the class of purchasers of graphite electrodes, Dr. Hartman developed econometric models to assess the impact of alleged antitrust violations.

2003: Working as a consulting expert for counsel to the class of direct purchasers, Dr. Hartman

reviewed materials in a matter regarding antitrust allegations concerning the manufacture and sale of microcrystalline cellulose in the United States.

2003: Working as a consulting expert to counsel for a large electrical generation company, Dr. Hartman developed economic and econometric models to analyze the allegation that this electrical generation company participated in a conspiracy to manipulate prices of power sold in California.

2003: Working as the testifying expert, Dr. Hartman submitted testimony which analyzed and calculated the economic impacts and damages to the U.S. growers and quota holders of flue-cured and burley tobacco leaf caused by a price-fixing conspiracy among the major U.S. tobacco leaf buyers and cigarette manufacturers.

2004: Working as the consulting expert for the United States Department of Justice, Dr. Hartman critically analyzed the calculation of the economic damages borne by an electric power generation utility as a result of the breach of the Standard Contract with the U.S. Department of Energy to remove spent nuclear fuel in 1998. Dr. Hartman's analysis included a critical review and rebuttal of the models and data put forward by the utility's experts in the calculation of damages; the development and presentation of alternative and improved models and corrected data to more accurately calculate damages; a critical review of econometric analyses put forward by one of the utility's experts; and a review of the economics of re-licensing existing nuclear generating facilities.

2004: Working as the testifying expert, Dr. Hartman submitted testimony in support of the certification of the class of purchasers of electrical carbon products who have been alleged to have been impacted and injured economically as a result of a price-fixing customer-allocation conspiracy of the major suppliers of such products in the United States.

2004-Present: Working as the testifying expert, Dr. Hartman submitted testimony in support of the certification of the class of end payer purchasers of those pharmaceutical products produced by AstraZeneca, the Bristol Myers Squibb Group, the Johnson and Johnson Group, the Glaxo-Smith-Kline Group and the Schering Plough Group that were subject to an alleged scheme to fraudulently inflate their Average Wholesale Price (AWP), thereby fraudulently inflating the reimbursement rates paid by the Class members for those pharmaceuticals when their reimbursement rates were formulaically related to the AWP. Dr. Hartman is consulting on related litigation undertaken by the Offices of the Attorneys General for the States of New York, Connecticut, Arizona, Nevada, Montana and Pennsylvania. He has also submitted testimony establishing liability and calculating damages for those Classes certified by the MDL Court and those States seeking remedy. 2004-2005: Working as a consulting expert to counsel for a major electricity and gas utility holding company, Dr. Hartman developed models to evaluate allegations of affiliate abuse by the regulated gas distribution entities and the trading entities of the holding company. The alleged abuses concerned spot and forward gas markets in California.

2005: Working as the testifying expert for the United States Department of Justice, Dr. Hartman developed models to critically analyze the cost submissions to the U.S. Court of Federal Claims by the TVA for monetary damages alleged to have resulted from partial breach by the U.S. Department of Energy of the Standard Contract to remove spent nuclear fuel from TVA beginning in 2002. Dr. Hartman's analysis included a critical review and rebuttal of the models, data and cost analyses put forward by the utility and the development and implementation of alternative and improved models and corrected data to more accurately calculate costs attributable to the alleged partial breach.

2005-2007: Working again as the testifying expert for the United States Department of Justice, Dr.

Hartman developed models to critically analyze the cost submissions to the U.S. Court of Federal Claims by the Systems Fuel Inc., a subsidiary of Entergy, for monetary damages alleged to have resulted from partial breach by the U.S. Department of Energy of the Standard Contract to remove spent nuclear fuel from SFI facilities in Mississippi and Arkansas. Dr. Hartman's analysis has included a critical review and rebuttal of the SFI models, data and cost analyses put forward by the utilities and the development and implementation of alternative and improved models and corrected data to more accurately calculate costs attributable to the alleged partial breach.

SELECTED TESTIMONY OF RAYMOND HARTMAN AT DEPOSITION, HEARING OR TRIAL

1995

The Economic Effects of Repealing the Prime Time Access Rule: Impact on Broadcasting Markets and the Syndicated Program Market, report presented in informal hearings before the Federal Communications Commission, MM Docket No. 94-123, March 7, 1995

Gillam v. Abex, et. al., San Francisco Superior Court No. 966241, 1995 (deposition)

Trilogy Communications Inc. v. Times Fiber Communications & LPL Technologies Inc., United States District Court for the Southern District of Mississippi, Jackson Division, Civil Action No. J91-0542 (W)(S), 1995 (deposition)

1996

Hall v. Abex, et. al., San Francisco Superior Court No. 958853, 1996 (deposition)

Sowers v. Abex, et. al., San Francisco Superior Court No. 949184, 1996 (deposition)

1997

Hillenbrand v. INA/Aetna, Sacramento County Superior Court No. 519223, 1997 (deposition)

1998

Hillenbrand v. INA/Aetna, Sacramento County Superior Court No. 519223, 1998 (trial)

Trilogy Communications Inc. v. Pennie & Edmonds, LLP, et. al., United States District Court for the Southern District of Mississippi, Jackson Division, Civil Action No. CIV-3:97CV722BN (deposition)

Paper Systems Incorporated v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd. (Civil Action No. 96-C-959), consolidated with *Graphic Controls Corp. v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Appleton Papers, Inc.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd.* (Civil Action No. 97-C-412) and *Victor Paper Roll Products, Inc. v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Appleton Papers, Inc.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd*. (Civil Action No. 97-C-508), United States District Court for the Eastern District of Wisconsin (deposition)

1999

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of The Massachusetts Attorney General in. re The Joint Petition of Eastern Enterprises and Colonial Gas Company for Approvals of Merger Pursuant to G.L.c. 164 " 96 and 94, before the Department of Telecommunications and Energy, D.T.E. 98-

128 (hearing)

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of The Massachusetts Attorney General in re The Joint Petition of Boston Edison Company, Cambridge Electric Light Company, Commonwealth Electric Company, and Commonwealth Gas Company for Approval of Rate Plan Pursuant to G.L.c. 164 " 76 and 94, before the Department of Telecommunications and Energy, D.T.E. 99-19 (hearing)

2001

Oral testimony before the International Trade Commission regarding the impacts of imports, domestic demand and factor price changes upon the prices of domestically produced carbon steel flat products and carbon steel long products during the Section 201 Hearings (No. TA-201-073 (final))

2002

In re Terazosin Hydrochloride Antitrust Litigation, Case No. 99-MDL-1317 Seitz/Garber, consolidated, United States District Court for the Southern District of Florida, (deposition on affirmative and rebuttal testimony in support of class certification and deposition on affirmative testimony on damage analysis)

In re Buspirone Antitrust Litigation, United States District Court, Southern District of New York, MDL Docket No. 1410 (deposition on affirmative and rebuttal testimony on class certification)

Anne Cunningham and Norman Mermelstein, Individually and on Behalf of all Others Similarly Situated, v. Bayer AG, Bayer Corporation, Barr Laboratories, Inc, The Rugby Group, Inc., Watson Pharmaceuticals, Inc. and Hoechst Marion Roussel, Inc., Index No. 603820-00, Supreme Court of the State of New York, County of New York (deposition on affirmative testimony on class certification)

In re Ciprofloxacin Hydrochloride Antitrust Litigation, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York. (deposition on affirmative testimony on class certification)

2003

In re Terazosin Hydrochloride Antitrust Litigation, Case No. 99-MDL-1317 Seitz/Garber, consolidated, United States District Court for the Southern District of Florida, (deposition on rebuttal testimony on damage analysis)

Anne Cunningham and Norman Mermelstein, Individually and on Behalf of all Others Similarly Situated, v. Bayer AG, Bayer Corporation, Barr Laboratories, Inc, The Rugby Group, Inc., Watson Pharmaceuticals, Inc. and Hoechst Marion Roussel, Inc., Index No. 603820-00, Supreme Court of the State of New York, County of New York (deposition on rebuttal testimony in support of class certification)

In re Ciprofloxacin Hydrochloride Antitrust Litigation, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York. (deposition on rebuttal testimony in support of class certification)

Cipro Cases I and II, Judicial Council Coordination Proceeding Nos. 4154 and 4220 (Superior Court, San Diego County) (depositions on affirmative and rebuttal testimony in support of class certification)

In re Relafen Antitrust Litigation, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY (depositions on affirmative and rebuttal testimony on class certification and affirmative testimony on damages)

Dr. Gregory Derderian, et. al., Plaintiffs, v Genesys Health Care Systems, et. al., Defendants, Case No. 99-64922-CK, State of Michigan, Circuit Court for the County of Genesee (testimony before arbitration panel)

In re D. Lamar DeLoach, et. al., Plaintiffs, v. Philip Morris Companies, Inc., et. al., Defendants, in the United States District Court for the Middle District of North Carolina, Greensboro Division, Case No. 00-CV-1235 (depositions on affirmative and rebuttal testimony calculating damages)

2004

In re Ciprofloxacin Hydrochloride Antitrust Litigation, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York (depositions on affirmative and rebuttal testimony calculating damages and affirmative and rebuttal testimony analyzing liability and market definition)

In re Lupron Marketing and Sales Practices Litigation, MDL No. 1430, CA No. 01-CV-10861, United States District Court, District of Massachusetts (deposition on affirmative testimony in support of class certification)

In re Pharmaceutical Industry Average Wholesale Price Litigation, United States District Court for the District of Massachusetts, MDL, No. 1456, CIVIL ACTION: 01-CV-12257-PBS (deposition on affirmative testimony in support of class certification)

2005

In re Lupron Marketing and Sales Practices Litigation, MDL No. 1430, CA No. 01-CV-10861, United States District Court, District of Massachusetts, (submission of written testimony at trial)

In re Tennessee Valley Authority, Plaintiff v. United States, Defendant, United States Court of Federal Claims, No. 01-249-C, (deposition and appearance trial)

Lynne A. Carnegie v. Household International, Inc., Household Bank, f.s.b., successor in interest to Beneficial National Bank, Household Tax Masters Inc., formerly known as Beneficial Tax Masters, Inc., Beneficial Franchise Company, Inc., H&R Block, Inc., H&R Block Services, Inc., H&R Block Tax Services, Inc., H&R Block Eastern Tax Services, Inc., Block Financial Corp. and HRB Royalty, Inc., No. 98 C 2178, United States District Court for the Northern District of Illinois Eastern Division, (submission of written testimony and deposition in calculation of damages)

2006

In re Pharmaceutical Industry Average Wholesale Price Litigation, United States District Court for the District of Massachusetts, MDL, No. 1456, CIVIL ACTION: 01-CV-12257-PBS (deposition testimony in calculation of damages in the MDL matter; submission of written testimony and deposition testimony in the calculation of damages and penalties for the State of Montana and the State of Nevada; submission of written testimony on summary judgment; submission of written testimony in support of class certification

in re Track 2 defendants; appearance at Track 1 trial)

State of Connecticut v. Dey, Inc., Roxanne Laboratories, Inc., Warrick Pharmaceuticals Corp., Schering-Plough Corp. and Schering Corporation; S*tate of Connecticut v. Pharmacia Corp.*, and *State of Connecticut v. Glaxo Smithkline et al*., Superior Court, Complex Litigation Docket at Tolland, Docket Nos. X07 CV-03-0083297-S, X07 CV-03-0083298-S, X07 CV-03-0083299-S (deposition on affirmative testimony on liability and the calculation of damages).

System Fuels, Inc., on its own behalf and as agent for System Energy Resources, Inc. and South Mississippi Electric Power Association, Plaintiff, v. The United States, Defendant, in the United States Court of Federal Claims, No. 03-2624C (deposition)

New England Carpenters Health Benefits Fund; Pirelli Armstrong Retiree Medical Benefits Trust; Teamsters Health & Welfare Fund of Philadelphia and Vicinity; and Philadelphia Federation of Teachers Health and Welfare Fund v. First Databank, Inc., and McKesson Corporation, United States District Court District of Massachusetts, C.A. No. 1:05-CV-11148-PBS (deposition)

In re Express Scripts, Inc., PBM Litigation, United States District Court Eastern District of Missouri Eastern Division, Master Case No. 4:05-md-01672-SNL (deposition on affirmative testimony in support of class certification).

In re Prempro Products Liability Litigation, in the United States District Court for the Eastern District of Arkansas, Western Division, MDL Docket # 4:03CV1507WRW; *In re Hormone Therapy Litigation*, in the Court of Common Pleas Philadelphia County, November 2003, #00001 (deposition)

In re: Neurontin Marketing and Sales Practices Litigation, MDL Docket No. 1629, Master File No. 04-10981, United States District Court, District of Massachusetts (deposition).

System Fuels, Inc., on its own behalf and as agent for Entergy Arkansas Inc., Plaintiff, v. The United States, Defendant, in the United States Court of Federal Claims, No. 2623C (deposition).

2007

System Fuels, Inc., on its own behalf and as agent for System Energy Resources, Inc. and South Mississippi Electric Power Association, Plaintiff, v. The United States, Defendant, in the United States Court of Federal Claims, No. 03-2624C (trial).

Attachment B

Attachment B: Documents Cited

Bates-Numbered Documents:

- AZ 0233062-106
- AZ 0492927
- AZ0004662-84
- AZ0004734-55
- AZ0022281-94
- AZ0092152-62
- FDB-AWP 15102-4
- FDB-AWP 02023

Manufacturer Data:

- AZ0466413-4
- AZ0682114
- AZ0687892-3

Depositions In re Pharmaceutical Industry Average Wholesale Price Litigation:

Bowman, Waldo, October 13, 2005
Brennan, David R., February 14, 2006
Chen, Thomas, December 14, 2005
Strand, Steven, June 17, 2005
Young, Steven J., November 18-19, 2004

Plaintiffs' Exhibits: 1, 2, 3, 4, 5, 12, 14, 15, 69, 105, 117, 118, 139, 142, 244, 245, 246.

Legal Documents:

Berndt, Ernst R., Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, February 9, 2005.

Complaint for Permanent Injunction and Other Equitable Relief Pursuant to Section 7A(g)(2) of the Clayton Act and Section 13(b) of the Federal Trade Commission Act, *Federal Trade Commission v. The Hearst Trust, The Hearst Corporation and First Databank, Inc.*, United States District Court for the District of Columbia, Civ. No. 1:01CV00734

Memorandum and Order re: Motion for Class Certification, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts,MDL No. 1456, Civil Action No. 01-12257.

Sentencing Memorandum of the United States, *United States of America v. TAP Pharmaceutical Products, Inc.*, United State District Court for the District of Massachusetts, Eastern Division, Criminal Action, No. 01-CR-10354-WGY.

Other Documents Cited:

42 CFR 405.517, Revised October 1, 1996 and October 1, 2003.

Alpert, Bill, "Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?" *Barron's*, June 10, 1996.

American Society of Clinical Oncology, "Reform of the Medicare Payment Methods for Cancer Chemotherapy," May 2001 (http://www.asco.org/asco/downloads/MedicarePaymentReform ASCOWhitePaper.pdf).

Ball, Robert M., "What Medicare's Architects Had in Mind," *Health Affairs*, 14(4), 1995.

Beck, Donald F., *Principles of Reimbursement in Health Care*, Aspen Publication, Rockville, MD, 1984.

The Benefits Improvement and Protection Act (BIPA) of 2000.

Berndt, E.R. "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs*, 20(2), 2001.

Centers for Medicare and Medicaid Services website: http://www.cms.hhs.gov.

Centers for Medicare and Medicaid Services website: http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp; accessed December, 2005.

Centers for Medicare and Medicaid Services, "Single Drug Pricer (SDP)," Program Memorandum: AB-02-174, December 3, 2002.

Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 54, December 24, 2003.

Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 352, November 3, 2004.

Department of Health and Human Services, Office of Inspector General, "Appropriateness of Medicare Prescription Drug Allowances," OEI-03-95-00420, May, 1996.

Department of Health and Human Services, Office of Inspector General, "Excessive Medicare Payments for Prescription Drugs," OEI-03-97-00290, December 1997.

Department of Health and Human Services, Office of Inspector General, "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," Federal Register, 68(86), p. 23731-23743, May 5, 2003.

Department of Health and Human Services, Office of Inspector General, "Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products," A-06-97-00011, August 1997.

Department of Health and Human Services, Office of Inspector General, "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, January 2001.

Department of Health and Human Services, Office of Inspector General, "Physicians' Costs for Chemotherapy Drugs," A-02-91-01049, November 1992.

Department of Health and Human Services, Office of Inspector General, "Medicare Reimbursement for Lupron," OEI-03-03-00250, January 2004.

Department of Health and Human Services, Health Care Financing Administration, Letter from Nancy-Ann Min DeParle, September 8, 2000.

Drug Topics, "Still growing: steady, not stellar, growth marked the pharmaceutical market last year," March 18, 2002.

Eppig, F.J. and Chulis, G.S. "Trends in Medicare Supplementary Insurance: 1992-96," *Health Care Financing Review*, 19(1), 1997.

Federal Register, January 7, 2004, 42 CFR 405 and 414, pp.1084-267.

Federal Register, Vol. 69, p. 66405-6.

Gaier, Eric M., Rebuttal Declaration, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, October 25, 2004.

General Accounting Office, "Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost," GAO-01-1118, September 2001.

Gencarelli, Dawn M, "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism," National Health Policy Forum Issue Brief No. 775, George Washington University, June 7, 2002.

Ginsburg, Paul B. and Joy M. Grossman, "When the Price Isn't Right: How Inadvertent Payment Incentives Drive Medical Care," *Health Affairs*, Vol. 24, pp. 376-384, Jul-Dec 2005.

Gould, John, Direct Testimony Declaration of Professor John P. Gould, November 10, 2006.

Hansen, M.T., "The search-transfer problem: The role of weak ties in sharing knowledge across organization subunits," *Administrative Science Quarterly*, 44(1), pp. 82-111, 1999.

Hartman, R., M. Doane and C.K. Woo, "Consumer Rationality and the Status Quo," *Quarterly Journal of Economics*, 106(1), pp. 141-162, 1991.

Henry J. Kaiser Family Foundation, "Medicare Restructuring: The FEHBP Model", (FEHBP Model), February 1999.

Jacobson, M., A. J. O'Malley, C. C. Earle, J. Pakes, P. Gaccione and J. P. Newhouse, "Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?" *Health Affairs*, Vol. 25, No. 2, pp. 437-443, Mar/Apr 2006.

Kaiser Family Foundation, State Health Facts website (www.statehealthfacts.org), accessed 2003.

Kaiser Family Foundation, State Health Facts website: http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=Medicare&subcategory=Medicare+Spending&topic=Total+Medicare+Benefit+Payments%2c+2001, accessed 3/14/07

Letter from Z. Bently, Ven-A-Care to Dr. Bruce Vladeck, HCFA, In Re Excessive Reimbursements for Certain Pharmaceuticals by the Medicare and Medicaid Programs, October 2, 1996.

MASSPIRG , "Health Care Reform – Prescription for Quality Health Care – The Average Wholesale Price (AWP) Litigation," (http://masspirg.org/MA.asp?id2=5310&id3=MA&).

McFadden, Daniel, Declaration of Direct Testimony by Daniel L. McFadden, PhD.

McFadden, Daniel, "Free Markets and Fettered Consumers," *American Economic Review*, Vol. 96, No. 1, pp. 5-29, 2006.

Medical Economics Company Inc., *Drug Topics Red Book*.

Medicare Payment Advisory Commission (MedPAC), "Report to the Congress: Variation and Innovation in Medicare," June 2003.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, December 8, 2003.

MedPAC, "Medicare Part B Drugs and Oncology," July 13, 2006.

Michael, Maureen, "Is the Medicare Policy in Several States to Restrict Access to Vitamin D For Dialysis Patients Heading in the Wrong Direction?," Focus on Nutrition: Opinion, Contemporary Dialysis & Nephrology, http://www.ikidney.com/iKidney/InfoCenter/Library/CDN/Archive/VitaminD0802.htm.

Pear, Robert, "Administration Plans Cuts in Some Drug Payments," *The New York Times*, August 6, 2000.

Prescription Drug Marketing Act of 1987 as modified by the Prescription Drug Amendments of 1992 (P. L. 102-353, 106 Stat. 941) on August 26, 1992

Rozek, Richard P. and Ruth Berkowitz, "The Costs to the U.S. Health Care System of Extending Marketing Exclusivity for Taxol," *Journal of Research in Pharmaceutical Economics*, 9(4), 1999.

Scully, Thomas, CMS Administrator, Testimony to the Senate Finance Committee Subcommittee on Health, March 14, 2002.

Scully, Thomas, CMS Administrator, Testimony to the U.S. House Energy and Commerce Subcommittees on Oversight & Investigations and Health on Part B drug reimbursement, March 21, 2002.

The Segal Company, "1999 Survey of State Employee Health Benefit Plans" (Segal Report)

Social Security Act Amendments of 1965 ("Medicare").

Spears, James M. and Jeff Pearlman, "Using Litigation to Regulate Drug Prices: The Assualt on 'AWP,'" Washington Legal Foundation, Critical Legal Issues, Working Paper Series No. 107, February 2002.

Szulanski, G., "Exploring internal stickiness: Impediments to the transfer of best practice within the firm," *Strategic Management Journal*, 17, pp. 27-43, 1996.

Tirole, Jean, *The Theory of Industrial Organization*, MIT Press, 1995.

TRICARE/CHAMPUS 2002 Chartbook of Statistics, Section VII (FY 2001). (http://199.211.83.250/Reports/Chartbook/2002/section7.cfm accessed August 2003).

United States Government Accountability Office, "Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs," December 1, 2004, GAO-05-142R.

Young, Steve, Rebuttal Declaration, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, October 25, 2004.

(See Attachment D to this report for additional documents cited.)

Attachment C

Attachment C: Medicare's Resource Based Relative Value Scale

C.1 Overview of the CMS RBRVS

1. Physicians and TPPs both benefit from having a relative value scale (RVS) that can be used as a basis of payment negotiations. HCFA, in cooperation with representatives of the American Medical Association (AMA) and societies of specialty physician providers, sponsored research in the early 1990s to develop the Resource-Based Relative Value Scale (RBRVS) to pay physicians under Part B on the basis of the thousands of procedures they perform. CMS maintains the RBRVS (modifying it over time). CMS also changes payment levels by specifying "update" factors; for example, raising the payment level for the next year by 2.5% while maintaining the relative level of payments associated with various procedures.

2. CMS reliance upon an RVS is driven by transaction costs. This is a version of the "importance of being unimportant" phenomenon introduced by Professor Berndt. Because it is too costly to monitor and negotiate prices item-by-item, CPT-by-CPT, both payors and providers look for an economical way to calculate reimbursements due physicians that meet the goals of payment system.

3. The RBRVS for physician services under Part B has the following property:

(1) $V_i/V_j \approx C_i/C_j$

Specifically, the "value" V_i assigned to procedure i in relation to the value assigned to procedure j is approximately equal to the relative costs of the two procedures.

4. A good payment system based on RVS has two properties. First, it covers the costs of the contracting physicians and encourages them to participate in the "network;" specifically, some multiple "k" times the sum of all values provided $k\Sigma V_i$ = total cost = ΣC_i. Note that if each procedure is **valued at cost**, k = 1. Second, for the incentive properties of the

RVS payment system to be correct at the level of the individual procedure, the payment for the procedure kV_i conveys an appropriate positive margin over its cost, C_i. If (1) holds exactly (and marginal costs are constant) we can see that there will be exactly the same margin for each procedure; that is,

(1a) $kV_i/C_i = kV_j/C_j = m_i = m_j = m$

5. The purpose of developing the RBRVS was to create a relative payment methodology that would eliminate margins that were "too big" for some procedures (mainly surgical) and improve the margins on other procedures (mainly the "evaluation and management" type) that were too small. Although the objective of the RBRVS was to better equalize the "margins" in Equation (1a) (i.e., $m_i = m_j = m$) for alternative services, various compromises with reality make that equality only approximate. However, physicians do make decisions about rates of surgery and other procedures that are influenced by incentives in the payment system, as reflected by m_i and m_j. In order for those incentives to be neutral across procedures, the margins should be equalized at m.[1]

6. Finally note that m can be considered **the yardstick** for the neutral margin across all provider procedures designated by CPT codes i and j.

C.2 Relevance to Part B Drug Reimbursement

7. The AWP-based drug reimbursement system is analogous to the RBRVS for provider services. The AWP-payment methodology can be considered a relative value scale. The relative values are determined by the AWPs and the level of reimbursement paid. As above, a relative value scale is useful if Equation (1) holds approximately, or, in the case of AWP if:

[1] For a recent discussion of the desirability of this property of the RVS, see (Ginsburg, Paul B. and Joy M. Grossman, "When the Price Isn't Right: How Inadvertent Payment Incentives Drive Medical Care", *Health Affairs*, Jul-Dec 2005, 24, pp 376-384).

(2) $AWP_i/AWP_j \approx ASP_i/ASP_j$

8. As above, a payment system based on the AWP should have two properties. First, it should allow for coverage of the costs of all pharmaceuticals reimbursed as part of the practice of all network physicians; specifically, some multiple "k" times the sum of all values (here AWPs) = $k\Sigma_i AWP$ = total provider cost = $\Sigma_i ASP_i$. Note that if drug claims are reimbursed at provider acquisition cost, $kAWP_i = ASP_i$ and $k= ASP_i/AWP_i$. Note also that if the value of drug i is set equal cost, ASP, k = 1 for all i and j. This is certainly the desired result of the *OIG Compliance Program Guidance* introduced in ¶ 3 of my Report. This is certainly the interpretation of the "plain meaning rule." Second, for the incentive properties of the RVS payment system to be correct, we expect at the level of a specific drug therapy, the payment for the value of drug therapy i (AWP_i) conveys an appropriate signal for its cost, ASP_i. Again, if (2) holds exactly, we can see that there should be exactly the same margin for each drug therapy i and j; that is,

(2a) $AWP_i/ASP_i = AWP_j/ASP_j = m_i = m_j = m$

9. In the case of drug therapies, the purpose of the RVS is to insure a relative payment methodology that eliminates margins that are "too big" for some drugs and "too small" for others. As with provider services (Equation (1a)), physicians do make decisions about which drugs to prescribe based upon the incentives in the drug reimbursement system, as reflected by m_i and m_j.[2] In order for those decisions to be neutral across drug therapies, the margins have been designed by CMS to be equalized at m.

[2] For a recent discussion of the how doctors respond to these margins in prescribing alternative drug therapies and regimens, Jacobson, Mireille, A. James O'Malley, Craig C. Earle, Juliana Pakes, Peter Gaccione, and Joseph P. Newhouse, "Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?" *Health Affairs*; Mar/Apr 2006; Vol. 25, No. 2, pp 437-443.

10. Note however that while HCFA and CMS have designed the RBRVS system so that m_i and m_j will be approximately equalized, in the context of drugs it is precisely these margins that have been manipulated by manufacturers as part of the AWP Inflation Scheme to move market share of drug i over drug j. The manipulation has occurred through the inflation of AWP and/or the concomitant reduction of ASP, everything else equal. Note further that based upon its RBRVS practices and procedures, Medicare and TPPs expected or anticipated the following:

- Equations (2) and (2a) held.
- AWPs embodied the properties of a RVS; i.e., were characterized by Equations (2) and (2a).
- That a summary measure of spread, m, characterized the relationship between the relative value measure (AWP) and the resource costs (ASP).
- m = 1 under the *OIG Compliance Program Guidance* and the "plain meaning" interpretation of AWP.

13. Unless these conditions characterized CMS, TPP and provider expectations, neither party would agree to use AWP as a RVS. *It would be economically irrational for Medicare or a private TPP to agree to a formula for payment that arbitrarily created incentives for overuse and/or under use of drugs*.[3]

[3] Research shows that differential margins on procedures and drugs affects physician behavior, *Ibid.* Payors (Medicare and private TPPs) have a goal not only of enlisting physicians in networks, but inducing them to provide appropriate care. An RVS with relative values unrelated to costs would confer arbitrary undesirable incentives and undermine the economic value of the health insurance offered by Medicare and by private TPPs.

Attachment D

Attachment D.1 Through D.3: Review of OIG and Other Industry Reports

Report Author	Report Title	Report	Report Date	Spread	Methodology of Spread Calculation	Type of Drug(s)
D.1 Brand and Generic Drugs Sold at Retail						
OIG	Use of AWP in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program	OIG	October 1989	AWP and ASP	Obtained prices from drug wholesalers and compared to "national drug pricing authorities" including Medispan and the Blue Book. Average discount for single and multi-source drugs was 15.5%	Sample of fifty-five single and multi-source drugs purchased by pharmacies.
GAO	Prescription Drugs: Changes in Prices for Selected Drugs	GAO	August 1992	Dollar Based	Comparison of AWP and other prices to determine changes in prices in relation to industry CPIs	Generic and brand drugs sold at pharmacy
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs	A-06-96-00030	April 1997	AWP Based	Invoice price as a percentage below AWP	Medicaid-covered brands sold at pharmacies
OIG	Semiannual Report, April 1, 1997 - September 30, 1997	OIG (DHHS)	April-Sept 1997	AWP Based	Based on OIG Reports. EAC percentage discount for brand and generic drugs off of AWP	Medicaid-covered brands sold at pharmacies
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products	A-06-00-00023	August 2001	AWP Based	The discount below AWP at which pharmacies purchase brand-name drugs	Medicaid-covered brands sold at pharmacies
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products	A-06-01-00053	March 2002	AWP Based	The discount below AWP at which pharmacies purchase generic drugs	Medicaid-covered generics sold at pharmacies
OIG	Medicaid Pharmacy - Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products	A-06-02-00041	September 2002	AWP Based	The discount below AWP at which pharmacies purchase generic drugs	Medicaid-covered generics sold at pharmacies
George Reeb	Testimony of George Reeb	CMS	October 2002	AWP Based	The discount below AWP at which pharmacies purchase generic and brand drugs	Generic and brand drugs sold at pharmacy
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products	A-06-97-00011	August 1997	AWP Based	The discount below AWP at which pharmacies purchase generic drugs	Medicaid-covered generics sold at pharmacies
CBO	Medicaid's Reimbursements to Pharmacies for Prescription Drugs	CBO	December 2004	Medicaid Price Ratio (AWP)	The difference between what Medicaid pays a pharmacy and the cost of acquiring the drug from the manufacturer, divided by Medicaid's payment	Medicaid-covered generics and brands
George Reeb	Testimony of George Reeb	CMS	December 2004	AWP Based	Percentage below AWP	Generic and brand drugs sold at pharmacy
Hearing	Medicaid and AWP Hearing: Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much	Federal Hearing	December 7, 2004	AWP and ASP	Hearing discusses both: markup over the acquisition cost and the discount off of AWP.	Medicaid-covered generics sold at pharmacies
D.2 Albuterol Sulfate						
OIG	Medicare Payments for Nebulizer Drugs	OEI-03-94-00390	February 1996	Dollar Based	Suggests that Medicare should use EAC for reimbursement of nebulizer drugs rather than AWP	Nebulizers (Albuterol Sulfate and others)
OIG	Suppliers' Acquisition Costs for Albuterol Sulfate	OEI-03-94-00393	June 1996	Dollar Based	Comparison of Medicare reimbursement amounts and estimated acquisition/supplier costs	Albuterol
OIG	A Comparison of Albuterol Sulfate Prices	OEI-03-94-00392	June 1996	Medicare Price (AWP) Based	Comparison of Medicare reimbursement amounts and estimated acquisition/supplier costs	Albuterol
OIG	Are Medicare Allowances for Albuterol Sulfate Reasonable?	OEI-03-97-00292	August 1998	ASP Based	Medicare allowed up to 333% more than acquisition costs for albuterol	Albuterol
OIG	Medicare Reimbursement of Albuterol	OEI-03-00-00311	June 2000	Medicare Price (AWP) Based	Difference between the prices, divided by the Medicare reimbursement price	Albuterol
OIG	Excessive Medicare Reimbursement for Albuterol	OEI-03-01-00410	March 2002	Medicare Price (AWP) Based	Calculated as the percentage below the Medicare Allowable Amount, or as a ratio vs. the VA price	Albuterol
Tom Gray	Construction Ahead	*Homecare*	October 1, 2002	EAC, WAC, VA Based	Refers to a previously published OIG report. Ratio to the VA price. Medicare is more than 9x higher than the VA price and higher than EAC.	Albuterol and Ipratropium Bromide
OIG	Update: Excessive Medicare Reimbursement for Albuterol	OEI-03-03-00510	January 2004	Dollar Based	Prices are compared, but no percentages are calculated	Albuterol
D.3 Medicare Part B and Physician Administered Drugs						
OIG	Physicians' Costs for Chemotherapy Drugs	A-02-91-01049	November 1992	AWP Based	Expressed as the invoice costs' percentage below the AWP	Chemotherapy drugs
Bill Alpert	Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals	*Barron's*	June 1996	AWP Based	Comparison of AWP and wholesale prices of about 300 dose forms. Article highlights a select number of PA drugs.	PA Medicare Part B generic and single-source drugs
OIG	Excessive Medicare Payments for Prescription Drugs	OEI-03-97-00290	December 1997	ASP Based	Reported as the Medicare allowed amount as a percentage above the average acquisition cost	Twenty-two of the top thirty Medicare Part B drugs with the highest total Medicare payments in 1995
Bozek and Berkowitz	The Costs to the US Health Care System of Extending Marketing Exclusivity for Taxol	*Journal of Research in Pharm Econ*	1999	AWP Based	Calculated as the percentage ratio of manufacturer price over the AWP	Taxol and a few other cancer drugs
Robert Pear	Administration Plans Cuts in Some Drug Payments	*The New York Times*	August 6, 2000	EAC/ASP Based	Describes the markups received by doctors as a percentage over their cost (up to 700%). Cites a 1997 DHHS cost based report.	PA Medicare Part B oncology drugs. Report cited 1997 DHHS study of 22 drugs
DHHS	Letter from Nancy-Ann Min DeParle	DHHS (HCFA)	September 8, 2000	Dollar Based	DOJ-collected pricing data compared to AWPs in Redbook. Dollar spread reported for only one example.	Reference to about 400 NDCs of 49 Medicare covered drugs
OIG	Medicare Reimbursement of Prescription Drugs	OEI-03-00-00310	January 2001	Dollar Based	Comparison is within Medicare and to VA and Medicaid Reimbursement, not comparing to ASP	Twenty-four of the top thirty Medicare Part B drugs with the highest total Medicare payments in 1999

Attachment D.1 Through D.3: Review of OIG and Other Industry Reports

Report Author	Report Title	Report	Report Date	Spread	Methodology of Spread Calculation	Type of Drug(s)
ASCO	Reform of the Medicare Payment Methods for Cancer Chemotherapy	ASCO	May 2001	AWP Based	Spreads calculated based on difference between wholesaler prices and AWP for Medicare reimbursement	Oncology drugs
GAO	Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost	GAO-01-1118	September 2001	AWP Based	The discount below AWP at which providers and physicians are acquiring the drugs	PA Medicare Part B drugs
MASSPIRG	Health Care Reform - Prescription for Quality Health Care - The AWP Litigation	MASSPIRG	December 20, 2001	AWP Based	Cites discounts off of AWP. This is a press release from the PAL, describing this AWP litigation and cites the complaint.	Refers generally to drugs in this litigation.
Spears and Pearlman	Using Litigation to Regulate Drug Prices: The Assault on AWP	*Washington Legal Foundation*	February 2002	AWP Based	Cites the Nov 1992 OIG report, which is AWP based	Chemotherapy drugs
Dawn M. Gencarelli	AWP for Prescription Drugs: Is There a More Appropriate Pricing Mechanism	National Health Policy Forum Issue Brief	June 7, 2002	AWP Based	Based on GAO-01-1118. The discount below AWP at which providers and physicians are acquiring the drugs	PA Medicare Part B drugs
MedPAC	Report to Congress: Variation and Innovation in Medicare	MedPAC	June 2003	AWP Based	Reports provider costs as a percentage of AWP	Medicare and Medicaid drugs
Federal Register	Fed Reg 42 CFR 405 and 414	Fed Reg	August 20, 2003	AWP Based	Cites the Nov. 1992 OIG report, which is AWP based	Chemotherapy drugs
OIG	Medicare Reimbursement for Lupron	OEI-03-03-00250	January 2004	Dollar Based	Prices are compared, but no percentages are calculated	Lupron and Zoladex
GAO	Medicare Chemotherapy Payments: New Drug and Administration Fees are Closer to Providers' Costs	GAO-05-142R	December 2004	AWP Based	Spreads are calculated based on difference between oncologists' EAC and Medicare reimbursement	Chemotherapy drugs

Attachment D.4: Summary of OIG and Other Available Reports for Medicare Part B and Physician Administered Drugs

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi Reported?
OIG, Physicians' Costs for Chemotherapy Drugs (A-02-91-01049), November 1992				
13	*Chemotherapy drugs*	*Spreads reported as the percentage below the AWP.*	*Yes*	*Yes*
6	Single-source drugs	Reported single-source spreads at 20% (manufacturer price); or 12-18% (oncology wholesaler price)		
7	Multi-source drugs	Reported multi-source spreads at 20-83% (manufacturer price); or 9-83% (oncology wholesaler price)		
Bill Alpert, Hooked On Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals? Barron's, June 1996				
13	*"Off Patent" Medicare Part B drugs*	*Spreads reported as the percentage of actual wholesale costs below AWP for off patent Part B drugs.*	*Yes*	*Yes*
	Single-source drugs	Spreads for single source drugs (e.g. Taxol and Platinol) "still enjoying patent protection" are reported to be generally 10-20% below AWP.		
13	Multi-source drugs	Average reported spread for 13 "off patent" multi-source drugs at 81% based on 1995 data (range from 58% to 93%)		

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi Reported?
OIG, Excessive Medicare Payments for Prescription Drugs (OEI-03-97-00290), December 1997				
22	*Medicare Part B drugs*	*Percent savings if drugs were purchased at the ACTUAL average wholesale price.*	*No*	*No*
11	Single-source drugs	Average reported savings for 11 single-source drugs at 22.5% in 1995 and at 19.5% in 1996. Excluding Novantrone from 1995 and Kytril and Zofran in 1995 and 1996, the savings ranged from 15%-24% in 1995 and 13%-21% in 1996. (Novatrone was an outlier at 52% in 1995.)		
9	Multi-source drugs	Average reported savings for 9 multi-source drugs at 69% in 1995 and 64% in 1996.		
2	Multi-brand drugs	Average reported savings for 2 multi-brand drugs was 46% in 1995 and 42% in 1996. This ranged from 17%-74% in 1995 and 13%-71% in 1996.		

Note: The OIG Report analyzes 22 drugs and states there 10 single-source, 9 multi-source and 3 multi-brand drugs. However, they did not identify how they classified each drug. Our analysis indicates that of these 22, 11 were single-source, 9 were multi-source and 2 were multi-brand.

Rozek and Berkowitz, The Costs to the US Health Care System of Extending Marketing Exclusivity for Taxol, Journal of Research in Pharmaceutical Economics, 1999				
4	Multi-source BMS cancer drugs	Spreads reported as the "intermediary margin" or the manufacturer price as a percentage below the AWP.	*Yes*	*Yes*
4	Multi-source drugs	Average spread for 4 BMS multi-source cancer drugs at 45.5% for the generic sources and 22.6% for the BMS brand from 1991-1996 (Table 2).		

Robert Pear, Administration Plans Cuts in Some Drug Payments, The New York Times, August 6, 2000				
	Medicare Part B drugs	Includes a summary of the December 1997 OIG Report (see above for actual spreads) and a general description of spread levels. No specific drugs or J-codes are listed in this article.	*No*	*No*

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi Reported?
DHHS, Letter from Nancy-Ann Min DeParle, September 8, 2000				
	Medicare Part B	DOJ-collected pricing data compared to AWPs in Redbook. Dollar spread reported for only one example.Reference to about 400 NDCs of 49 Medicare covered drugs	*No*	*No*
OIG, Medicare Reimbursement of Prescription Drugs (OEI-03-00-00310), January 2001				
24	*Medicare Part B drugs*	*Percent savings if drugs were purchased at the catalog median price instead of the Medicare median.*	*No*	*No*
17	Single-source drugs	Average savings for 17 single-source drugs at 16.3% based on 1999 data. After excluding Anzemet/dolasetron mesylate (44.1%) and Kytril/granisetron HCl (25.5%) all other reported savings are less than 17%.		
7	Multi-source drugs	Average savings for 7 multi-source drugs at 51.4% based on 1999 data. After excluding Lupron (15.8%) all savings are greater than 24%.(Lupron was an outlier at 15.8%).		
ASCO, Reform of the Medicare Payment Methods for Cancer Chemotherapy, May 2001				
	Oncology drugs	*Considered spreads to be the difference between AWP and actual selling price. Cited OIG (Nov 1992) report.*	*No*	*No*

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi Reported?
GAO, Medicare: Payments for Covered Outpatient Drugs Exceed Providers Costs (GAO-01-1118), September 2001				
	25 Medicare Part B drugs	*Average widely available discount from AWP reported for 25 Medicare-covered drugs. Six other drugs were considered but spreads were not reported.*	*Yes*	*No*
	16 Single-source drugs	Average spread for 16 single-source drugs equaled 22.1%. Excluding Anzement, the spreads range from 12.8% to 29.3%. (Anzemet was an outlier at 65%).		
	9 Multi-source drugs	Average spread for 9 multi-source drugs at 59.2%. Excluding Lupron and dexamethasone sodium phosphate the spreads ranges from 34.4% to 85.6%. (Lupron and dexamethasone sodium phosphate were outliers at 17.6% and 14%, respectively.)		
MASSPIRG, Health Care Reform - Prescription for Quality Health Care - The AWP Litigation, December 20, 2001				
	Drugs subject to the AWP litigation	*This PAL news release describes this litigation and references a range of discounts off AWP from 13-34% to 65-85%. No drug-specific spreads are reported in this news release.*	*Yes*	*No*
Washington Legal Foundation, Using Litigation to Regulate Drug Prices: The Assault on AWP, February 2002				
	Chemotherapy drugs	*White paper by Ropes and Gray attorneys. Cites the Nov 1992 OIG report, which is AWP based*	*No*	*No*
AWP for Prescription Drugs: Is There a More Appropriate Pricing Mechanism, National Health Policy Forum Issue Brief, June 7, 2002				
	PA Medicare Part B drugs	*Cites several OIG reports, but other than one illustrative example, does not list any specific drug prices. Refers to GAO-01-1118.*	*No*	*No*
MedPAC, Report to Congress: Variation and Innovation in Medicare, June 2003				
	Medicare and Medicaid drugs	*Reports provider costs as a percentage of AWP*	*No*	*No*

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi Reported?
Federal Register, Fed Reg 42 CFR 405 and 414, January 7, 2004				
	Medicare Part B drugs	*Reports spreads from the September 2001 GAO report and the January 2001 OIG report (see above for descriptions of spreads reported), plus others.*	*Yes*	*Yes*
20	*Single-Source*	*Spreads are calculated based on previously reported values for 20 single source drugs with an average of 16% spread. (Kytril and Anzemet were outliers at 25% and 41%, respectively). Excluding Kytril and Anzemet all other spreads were less than 18% (8% to 17%).*		
9	*Multiple-Source*	*Spreads are calculated based on previously reported information on 9 multiple source drugs with an average of 54%. Other than dexamethosone sodium phosphate (9%) the generic spreads ranged from 24% to 84%.*		
OIG, Medicare Reimbursement for Lupron (OEI-03-03-00250), January 2004				
		Prices are compared, but no percentages are calculated	*No*	*No*
GAO, Medicare Payments to Oncologists (GAO-05-142R), December 1, 2004				
16	*Medicare Part B drugs*	*Spreads calculated as Payment-to-Cost ratios. Acquisition cost estimates were based on drug price data obtained from IMS. Payment-to-cost ratios for 16 drugs billed to Medicare by oncologists exceeded estimated costs by 22% in 2004. (This is a weighted average based on 2003 utilization.) This study was requested to "review the adequacy of Medicare payments for chemotherapy-related drugs and chemotherapy administration services..."*	*Yes*	*No*
13	Single-source drugs	Weighted average payment-to-cost ratio for 13 single-source drugs calculated at 14.2%		
3	Multi-source drugs	Weighted average payment-to-cost ratio for 3 multi-source drugs calculated at 376.2%.		

Attachment E

Attachment E.1.a: AstraZeneca Annual Average Sales Price

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	255.00	254.95	263.67	272.75	254.84	267.33	252.78	188.00	190.55	200.34	188.21	194.62	n/a	n/a
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot						805.05	690.04	517.69	523.55	537.78	538.75	537.90	n/a	n/a

Note: Data were not provided by AZ for 2003-2004.

Attachment E.1.b: AstraZeneca Annual AWPs

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	318.75	318.75	318.75	331.50	358.55	383.65	410.51	439.24	469.99	469.99	469.99	469.99	469.99	469.99
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot						1,208.49	1,231.53	1,317.74	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98

Attachment E.1.c: AstraZeneca Annual Spreads

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	25.00%	25.03%	20.89%	21.54%	40.70%	43.51%	62.40%	133.64%	146.65%	134.60%	149.71%	141.49%	n/a	n/a
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot						50.11%	78.47%	154.54%	169.31%	162.18%	161.72%	162.13%	n/a	n/a

Note: Data were not provided by AZ for 2003-2004.

Attachment E.1.d: AstraZeneca Total National Net Sales

NDC	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	Total
00310096036	Zoladex 3.6mg 1x1EA Depot	17,454,861	28,030,004	38,488,001	51,648,247	62,244,866	54,793,535	38,314,515	29,725,122	22,008,089	20,398,572	17,725,133	17,160,726	14,019,627	10,878,528	422,889,828
00310096130	Zoladex 10.8mg 1x1EA Depot	0	0	0	0	0	47,140,665	74,118,270	95,466,334	95,887,049	113,210,040	136,476,719	141,441,517	152,935,312	164,429,108	1,021,105,013
	Total	17,454,861	28,030,004	38,488,001	51,648,247	62,244,866	101,934,201	112,432,786	125,191,456	117,895,138	133,608,612	154,201,852	158,602,243	166,954,939	175,307,636	1,443,994,842

Note: To account for missing data in 2003-2004, net sales have been extrapolated using the trend from 1998 to 2002.

Source: ASP (Attachment E.1.a) multiplied by total national units.

Attachment E.2: AstraZeneca Electronic Data Calculation Notes

File List:
AZ0682114 (Zoladex_Sales.mdb: Zoladex direct and Indirect sales)
AZ0687892 (AZ files for AWP Litigation.mdb: Compass ID codes)
AZ0687893 (AZ Rebates for 1991-1994.mdb, Special Institutional Rebates for AWP Litigation.mdb)
AZ0466413 (AstraZeneca Rebates 5-21-2004.mdb)

Sources:
Direct Sales files: Direct sales tables for Zoladex; "AZ Sales Based Customers" for Compass ID codes.

Chargeback files : Indirect sales tables for Zoladex; "AZ Sales Based Customers" for Compass ID codes.

Rebate files: Rebate tables for Zoladex; Institutional rebates; Zoladex rebates for 1991-1994.

Direct Sales

- The following customer codes were deemed outside of the Class and were excluded:

ZA,	PP,	CD,	CO,	HN,	HO,	HT,	BP,	DC,	DD,	FS,
IS,	MT,	SV,	VA,	SH,	SO,	SU,	Z1,	HM,	HW,	SP,
DO,	OP,	EH,	EM,	HI,	IN,	ZC,	FG,	HA,	HF,	HP,
IP,	IR,	MM,	PA,	PH,	SG,	SM				

- The field WHSLR_COMPASS_ID was used to merge the Compass ID data set with the direct sales data (using the field SHIP_TO_CUST_ID in the direct sales data), adding a STATE field to the direct sales data.
- State codes "AA", "AE", "AP", "AS", "FM", "GU", "MH", "MP", "PR", "VI", "XX" were excluded to avoid counting non-U.S. sales.
- All records before July 1, 2000 where SALES_INDICATOR is "A" were deleted to avoid double-counting chargeback data. Note that this may also have deleted other non-chargeback credits as well.
- Quantity invoiced was calculated using the field QTY_PKGS_INVOICED, and dollars invoiced using the field INVOICE_AMOUNT.
- The field INVOICE_DATE was used as the sale date.
- Totals were calculated by year and by NDC.

Chargebacks

- The following customer codes were deemed outside of the Class and were excluded:

ZA,	PP,	CD,	CO,	HN,	HO,	HT,	BP,	DC,	DD,	FS,
IS,	MT,	SV,	VA,	SH,	SO,	SU,	Z1,	HM,	HW,	SP,
DO,	OP,	EH,	EM,	HI,	IN,	ZC,	FG,	HA,	HF,	HP,
IP,	IR,	MM,	PA,	PH,	SG,	SM				

- The same codes above were used to determine the amount of units and sales based on WAC that should be excluded from the total Class sales.
- The field WHSLR_COMPASS_ID was used to merge the Compass ID data set with the chargeback data (using the field WHSLR_COMPASS_ID in the chargeback data), adding a STATE field to the chargeback data.
- State codes “AA”, “AE”, “AP”, “AS”, “FM”, “GU”, “MH”, “MP”, “PR”, “VI”, “XX” were excluded to avoid counting non-U.S. sales.
- A field named WAC_AMT was created, and calculated as: NO_OF_PACKAGES*((CHARGE_BACK_AMOUNT/NO_OF_PACKAGES) + CONTRACT_PKG_PRICE)
- This WAC_AMOUNT field was used to calculate WAC dollars to exclude from the Class, and the field NO_OF_PACKAGES to calculate units to exclude from the Class.
- The field CHARGE_BACK_AMOUNT was used to calculate chargeback dollars paid to the Class.
- The field INVOICE_DATE was used.
- Totals were calculated by year and by NDC.

Rebates

- The following customer category codes were deemed outside of the Class and were excluded from the rebate data:

Closed Door, Outpati
Disproportionate Sha
Federal Government
Federal Gov't - Mili
Federal Gov't - VA M
Health Plan - IPA/PP
HMO - Mixed Model
HMO - Staff Model He
Hospital
Hospital Nominal Pri
Pharmacy Benefit Man
PHS Funded
Short Term Care - Cl
Short Term Care - Ph
State & Local Govern
State & Local Gov't

- In the rebate data, records with blank customer category codes, though minimal, were included.
- The field NDC11_DESCRIPTION was used to create a field named “ndc” in the rebate data.
- The fields REBATES and FEES were added together and used to calculate total rebate dollars paid to the Class. The field “Quarter” was used as the rebate date.
- Totals were calculated by year and by NDC.

Attachment F

Attachment F.1.a: Zoladex Damages for Class 1 Beneficiaries*

NDC	Description	Share**	x:	0.0% 1991	0.0% 1992	0.0% 1993	0.0% 1994	0.0% 1995	0.0% 1996	0.0% 1997	5.0% 1998	5.0% 1999	5.0% 2000	5.0% 2001	5.0% 2002	5.0% 2003	20.0% 2004	Total
00310096036	Zoladex 3.6mg 1x1EA Depot	1.83%		79,808	128,294	147,046	203,469	463,310	436,059	437,252	663,037	540,658	458,407	444,873	406,175	341,960	277,744	5,028,093
00310096130	Zoladex 10.8mg 1x1EA Depot	1.83%							432,065	1,063,746	2,476,106	2,733,111	3,086,670	3,709,923	3,854,991	4,199,712	4,544,433	26,100,758
	Total Nominal Zoladex Damages* **			**79,808**	**128,294**	**147,046**	**203,469**	**463,310**	**868,124**	**1,500,998**	**3,139,143**	**3,273,769**	**3,545,077**	**4,154,797**	**4,261,166**	**4,541,672**	**4,822,178**	**31,128,851**
	Total Through 2003															**26,306,673**		
	Average Treasury Rate****			4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	
	Number of Years			15	14	13	12	11	10	9	8	7	6	5	4	3	2	
	Total Damages Including Prejudgment Interest			**149,458**	**230,418**	**253,278**	**336,107**	**733,983**	**1,318,958**	**2,187,079**	**4,386,625**	**4,387,352**	**4,556,331**	**5,121,232**	**5,037,188**	**5,148,853**	**5,242,918**	**39,089,780**
	Total Through 2003															**33,846,863**		

Notes:

* The Class states are: Arizona, Arkansas, California, Colorado, Connecticut, Washington D.C., Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin and Wyoming.
The percentage of damages for these states (87%) was calculated using total Medicare estimated payments data from the Kaiser Family Foundation, accessed 3/14/07:
http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=Medicare&subcategory=Medicare+Spending&topic=Total+Medicare+Benefit+Payments%2c+2001.
** The share is equal to the 20% copayment * Medicare reimbursement percentage (76.2%, see Attachment F.3) * Beneficiary copayment percentage (13.8%) * Class states percentage (87%).
*** To account for missing data in 2003-2004, damages have been extrapolated by NDC using the trend from 1998 to 2002.
**** Source: Annual 1-Year US Treasury Rate (Constant Maturity). Average from 1991 to 2005.

Attachment F.1.b: Zoladex Damages for Class 1 Beneficiaries by State

State	Medicare Expenditures ($ millions)*	In Class 1?	Percent of Total Class 1 States	Total Through 2003		Total Through 2004	
				Nominal Damages to Class 1	Class 1 Damages with Prejudgment Interest	Nominal Damages to Class 1	Class 1 Damages with Prejudgment Interest
United States	245,186						
Alabama	4,058	No	0.0%	0	0	0	0
Alaska	254	No	0.0%	0	0	0	0
Arizona	3,777	Yes	1.8%	464,034	597,038	549,094	689,520
Arkansas	2,354	Yes	1.1%	289,207	372,102	342,221	429,741
California	26,920	Yes	12.6%	3,307,331	4,255,300	3,913,585	4,914,451
Colorado	2,527	Yes	1.2%	310,462	399,448	367,371	461,323
Connecticut	3,463	Yes	1.6%	425,456	547,404	503,445	632,197
Delaware	754	Yes	0.4%	92,635	119,186	109,615	137,648
District of Columbia	569	Yes	0.3%	69,906	89,943	82,720	103,875
Florida	19,935	Yes	9.3%	2,449,170	3,151,166	2,898,118	3,639,286
Georgia	5,486	No	0.0%	0	0	0	0
Hawaii	799	Yes	0.4%	98,163	126,300	116,157	145,864
Idaho	835	Yes	0.4%	102,586	131,990	121,391	152,436
Illinois	10,073	Yes	4.7%	1,237,546	1,592,260	1,464,396	1,838,903
Indiana	4,773	Yes	2.2%	586,400	754,478	693,891	871,347
Iowa	2,369	No	0.0%	0	0	0	0
Kansas	2,071	Yes	1.0%	254,438	327,367	301,079	378,077
Kentucky	3,601	No	0.0%	0	0	0	0
Louisiana	4,454	No	0.0%	0	0	0	0
Maine	1,119	No	0.0%	0	0	0	0
Maryland	4,675	Yes	2.2%	574,360	738,987	679,644	853,457
Massachusetts	6,651	Yes	3.1%	817,127	1,051,337	966,911	1,214,191
Michigan	9,227	Yes	4.3%	1,133,609	1,458,531	1,341,406	1,684,459
Minnesota	3,373	Yes	1.6%	414,399	533,177	490,361	615,767
Mississippi	2,604	No	0.0%	0	0	0	0
Missouri	5,010	Yes	2.3%	615,517	791,941	728,346	914,614
Montana	659	No	0.0%	0	0	0	0
Nebraska	1,325	Yes	0.6%	162,787	209,445	192,626	241,889
Nevada	1,496	Yes	0.7%	183,795	236,476	217,486	273,106
New Hampshire	879	Yes	0.4%	107,992	138,945	127,788	160,468
New Jersey	9,306	Yes	4.3%	1,143,314	1,471,019	1,352,891	1,698,881
New Mexico	1,107	Yes	0.5%	136,004	174,986	160,934	202,091
New York	19,403	Yes	9.1%	2,383,809	3,067,072	2,820,776	3,542,165
North Carolina	6,300	Yes	2.9%	774,004	995,854	915,884	1,150,113
North Dakota	479	Yes	0.2%	58,849	75,717	69,636	87,445
Ohio	10,139	Yes	4.7%	1,245,655	1,602,693	1,473,991	1,850,951
Oklahoma	3,044	Yes	1.4%	373,979	481,171	442,532	555,705
Oregon	2,596	Yes	1.2%	318,939	410,355	377,402	473,920
Pennsylvania	13,732	Yes	6.4%	1,687,083	2,170,645	1,996,336	2,506,881
Rhode Island	1,070	Yes	0.5%	131,458	169,137	155,555	195,337
South Carolina	3,429	Yes	1.6%	421,279	542,029	498,502	625,990
South Dakota	540	Yes	0.3%	66,343	85,359	78,504	98,581
Tennessee	4,847	Yes	2.3%	595,492	766,175	704,649	884,857
Texas	15,105	Yes	7.1%	1,855,767	2,387,678	2,195,940	2,757,533
Utah	1,004	Yes	0.5%	123,349	158,704	145,960	183,288
Vermont	480	Yes	0.2%	58,972	75,875	69,782	87,628
Virginia	4,798	No	0.0%	0	0	0	0
Washington	3,863	Yes	1.8%	474,600	610,632	561,597	705,220
West Virginia	1,907	Yes	0.9%	234,290	301,443	277,237	348,137
Wisconsin	3,948	Yes	1.8%	485,042	624,068	573,954	720,737
Wyoming	338	Yes	0.2%	41,526	53,428	49,138	61,704
Total, Class 1 States	214,123			26,306,673	33,846,863	31,128,851	39,089,780
Percent of US	87%						

* See notes in Attachment F.1.a.

Attachment F.2.a: Savings on Class 1 Medicare Payments Assuming Reimbursements Based on 106% of ASP

NDC	Description	Share	x:	0.0% 1991	0.0% 1992	0.0% 1993	0.0% 1994	0.0% 1995	0.0% 1996	0.0% 1997	5.0% 1998	5.0% 1999	5.0% 2000	5.0% 2001	5.0% 2002	5.0% 2003	20.0% 2004	Total
00310096036	Zoladex 3.6mg 1x1EA Depot	1.83%		60,653	97,535	104,811	146,792	395,004	375,930	395,207	630,418	516,507	436,023	425,422	387,344	326,575	265,806	4,564,027
00310096130	Zoladex 10.8mg 1x1EA Depot	1.83%							380,334	982,411	2,371,344	2,627,888	2,962,437	3,560,158	3,699,777	4,031,886	4,363,994	24,980,228
	Total Nominal Medicare Savings			**60,653**	**97,535**	**104,811**	**146,792**	**395,004**	**756,264**	**1,377,618**	**3,001,762**	**3,144,395**	**3,398,459**	**3,985,581**	**4,087,121**	**4,358,461**	**4,629,800**	**29,544,256**
	Total Through 2003															**24,914,455**		
	Average Treasury Rate			4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	4.27%	
	Number of Years			15	14	13	12	11	10	9	8	7	6	5	4	3	2	
	Total Savings Including Prejudgment Interest			**113,587**	**175,174**	**180,530**	**242,483**	**625,772**	**1,149,008**	**2,007,304**	**4,194,649**	**4,213,971**	**4,367,889**	**4,912,655**	**4,831,447**	**4,941,149**	**5,033,756**	**36,989,372**
	Total Through 2003															**31,955,616**		

Notes:
* See notes to Attachment F.1.a.

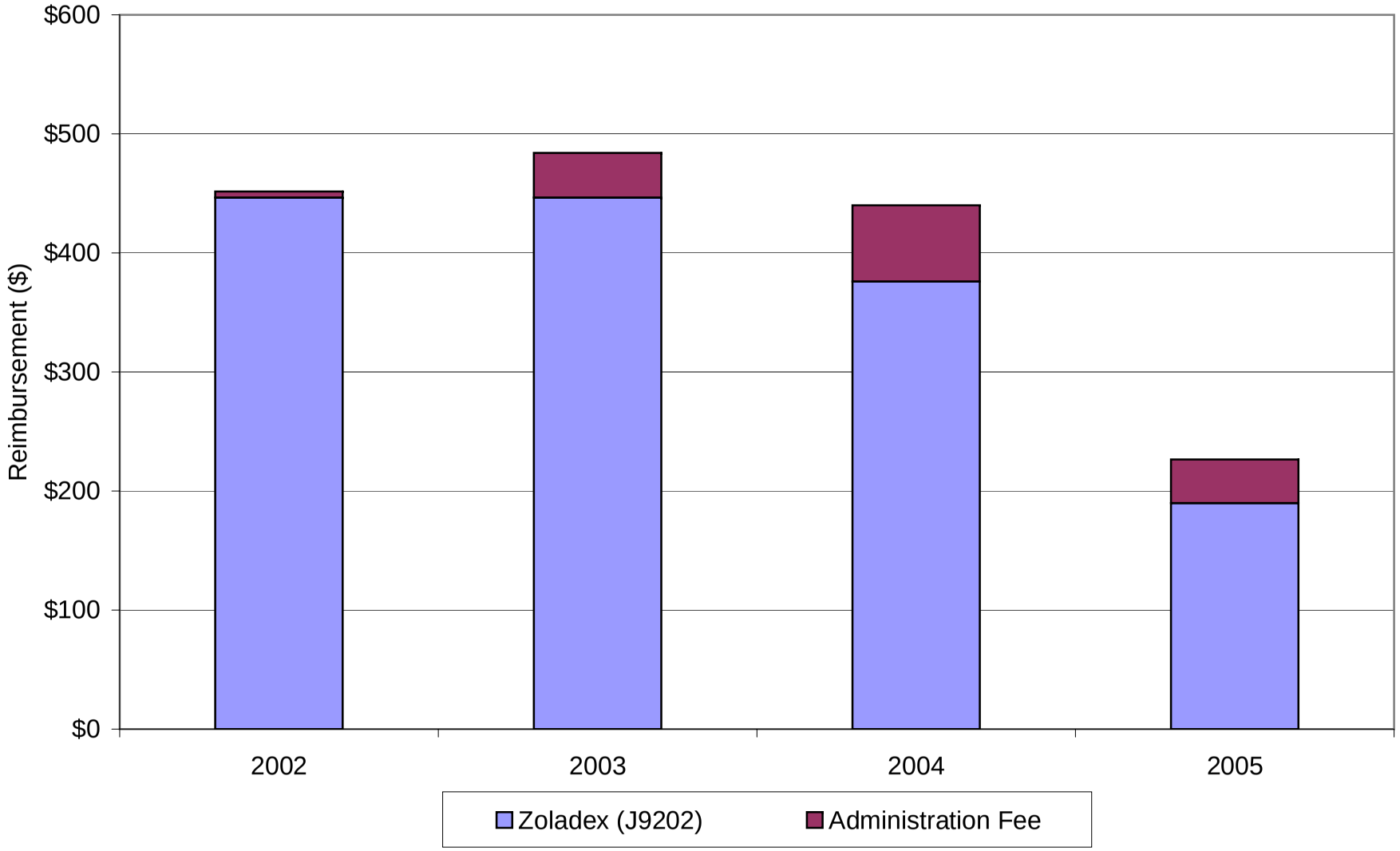
Attachment F.2.b: Savings on Class 1 Medicare Payments Assuming Reimbursements Based on 106% of ASP by State

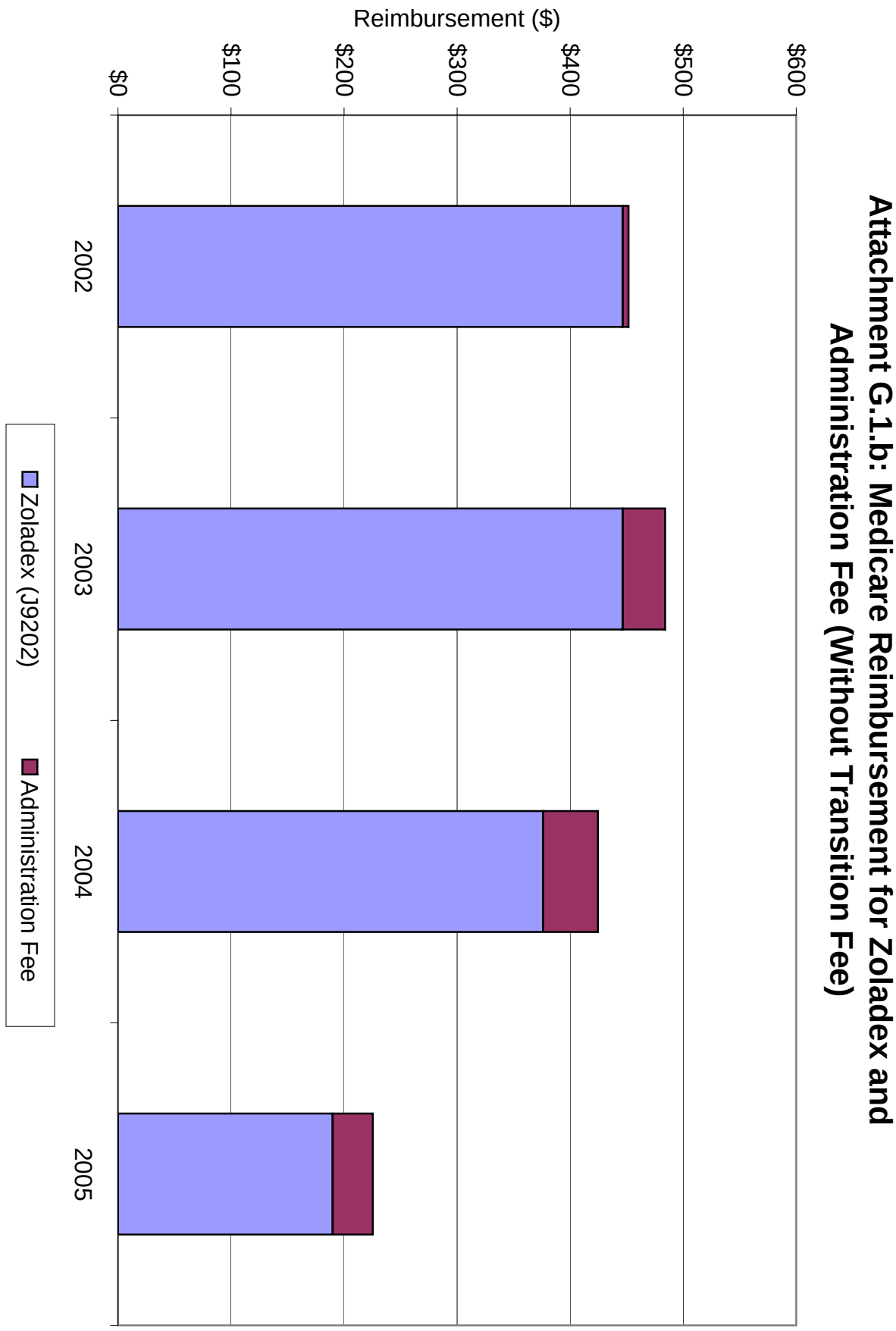
State	Medicare Expenditures ($ millions)*	In Class 1?	Percent of Total Class 1 States	Total Through 2003		Total Through 2004	
				Nominal Damages to Class 1	Class 1 Damages with Prejudgment Interest	Nominal Damages to Class 1	Class 1 Damages with Prejudgment Interest
United States	245,186						
Alabama	4,058	No	0.0%	0	0	0	0
Alaska	254	No	0.0%	0	0	0	0
Arizona	3,777	Yes	1.8%	439,476	563,678	521,143	652,470
Arkansas	2,354	Yes	1.1%	273,902	351,310	324,800	406,649
California	26,920	Yes	12.6%	3,132,298	4,017,528	3,714,367	4,650,383
Colorado	2,527	Yes	1.2%	294,031	377,128	348,670	436,535
Connecticut	3,463	Yes	1.6%	402,940	516,816	477,818	598,227
Delaware	754	Yes	0.4%	87,732	112,527	104,035	130,252
District of Columbia	569	Yes	0.3%	66,206	84,917	78,509	98,294
Florida	19,935	Yes	9.3%	2,319,553	2,975,090	2,750,591	3,443,736
Georgia	5,486	No	0.0%	0	0	0	0
Hawaii	799	Yes	0.4%	92,968	119,242	110,244	138,026
Idaho	835	Yes	0.4%	97,157	124,615	115,212	144,245
Illinois	10,073	Yes	4.7%	1,172,052	1,503,290	1,389,852	1,740,093
Indiana	4,773	Yes	2.2%	555,366	712,320	658,569	824,527
Iowa	2,369	No	0.0%	0	0	0	0
Kansas	2,071	Yes	1.0%	240,973	309,075	285,752	357,762
Kentucky	3,601	No	0.0%	0	0	0	0
Louisiana	4,454	No	0.0%	0	0	0	0
Maine	1,119	No	0.0%	0	0	0	0
Maryland	4,675	Yes	2.2%	543,963	697,695	645,047	807,598
Massachusetts	6,651	Yes	3.1%	773,882	992,592	917,691	1,148,949
Michigan	9,227	Yes	4.3%	1,073,615	1,377,033	1,273,123	1,593,948
Minnesota	3,373	Yes	1.6%	392,468	503,385	465,400	582,680
Mississippi	2,604	No	0.0%	0	0	0	0
Missouri	5,010	Yes	2.3%	582,943	747,690	691,270	865,469
Montana	659	No	0.0%	0	0	0	0
Nebraska	1,325	Yes	0.6%	154,171	197,742	182,821	228,891
Nevada	1,496	Yes	0.7%	174,068	223,262	206,415	258,431
New Hampshire	879	Yes	0.4%	102,277	131,182	121,283	151,846
New Jersey	9,306	Yes	4.3%	1,082,807	1,388,823	1,284,023	1,607,595
New Mexico	1,107	Yes	0.5%	128,806	165,208	152,742	191,232
New York	19,403	Yes	9.1%	2,257,652	2,895,695	2,677,186	3,351,834
North Carolina	6,300	Yes	2.9%	733,042	940,209	869,261	1,088,314
North Dakota	479	Yes	0.2%	55,734	71,486	66,091	82,746
Ohio	10,139	Yes	4.7%	1,179,732	1,513,140	1,398,959	1,751,494
Oklahoma	3,044	Yes	1.4%	354,187	454,285	420,005	525,846
Oregon	2,596	Yes	1.2%	302,060	387,426	358,191	448,454
Pennsylvania	13,732	Yes	6.4%	1,597,798	2,049,357	1,894,713	2,372,179
Rhode Island	1,070	Yes	0.5%	124,501	159,686	147,636	184,841
South Carolina	3,429	Yes	1.6%	398,984	511,742	473,126	592,354
South Dakota	540	Yes	0.3%	62,832	80,589	74,508	93,284
Tennessee	4,847	Yes	2.3%	563,977	723,364	668,779	837,311
Texas	15,105	Yes	7.1%	1,757,555	2,254,263	2,084,157	2,609,362
Utah	1,004	Yes	0.5%	116,821	149,836	138,530	173,439
Vermont	480	Yes	0.2%	55,851	71,635	66,229	82,919
Virginia	4,798	No	0.0%	0	0	0	0
Washington	3,863	Yes	1.8%	449,482	576,512	533,009	667,326
West Virginia	1,907	Yes	0.9%	221,891	284,600	263,124	329,431
Wisconsin	3,948	Yes	1.8%	459,373	589,198	544,737	682,010
Wyoming	338	Yes	0.2%	39,328	50,443	46,637	58,389
Total, Class 1 States	214,123			24,914,455	31,955,616	29,544,256	36,989,372
Percent of US	87%						

* See notes in Attachment F.1.a.

Attachment G

Attachment G.1.a: Medicare Reimbursement for Zoladex and Administration Fee (With Transition Fee)





Attachment G.1.b: Medicare Reimbursement for Zoladex and Administration Fee (Without Transition Fee)

Attachment G.1.c
Changes in Medicare Reimbursement for a Typical Administration of Zoladex Including Transition Fees

Year	Medicare Reimbursement Method	Medicare-Based AWP	Medicare Reimbursement for J9202 (includes copay amount)	Medicare Reimbursement for Code = 96400 (G0356 in 2005)[1]	Total Reimbursement	Change in Reimbursement from Previous Year
2002	95% awp	469.99	446.49	5.07	451.56	
2003	95% awp	469.99	446.49	37.52	484.01	32.45
2004	80% awp	469.99	375.99	64.07	440.06	-43.95
2005	1.06 asp		189.79	36.69	226.48	-213.58

Notes

1. Source: Federal Register, Vol. 69, p. 66405.

Attachment G.1.d
Changes in Medicare Reimbursement for a Typical Administration of Zoladex Without Transition Fees

Year	Medicare Reimbursement Method	Medicare-Based AWP	Medicare Reimbursement for J9202 (includes copay amount)	Medicare Reimbursement for Code = 96400 (G0356 in 2005)[1]	Total Reimbursement	Change in Reimbursement from Previous Year
2002	95% awp	469.99	446.49	5.07	451.56	
2003	95% awp	469.99	446.49	37.52	484.01	32.45
2004	80% awp	469.99	375.99	48.54	424.53	-59.48
2005	1.06 asp		189.79	35.62	225.41	-199.12

Notes

1. Source: Federal Register, Vol. 69, p. 66406.

Attachment G.2: Comparison of Direct Testimony ASPs with CMS ASPs

Manufacturer	Drug	J-Code	Range of Direct Testimony ASPs[1]	CMS ASP (1/05)	Are the Direct Testimony ASPs Greater than CMS ASPs?
AstraZeneca	Zoladex	J9202	$179.30 - $194.62	$179.04	Yes

Note

1. These ASPs were taken from the most recent complete year for which data were available (2002) from Attachment E.1.a. They were then converted to prices per fundamental billing unit.